



Clinical trial results:

A phase I-Ib/II, open-label, multi-center study of the safety and efficacy of MBG453 as single agent and in combination with PDR001 in adult patients with advanced malignancies

Summary

EudraCT number	2015-002354-12
Trial protocol	NL DE IT
Global end of trial date	30 August 2022

Results information

Result version number	v1 (current)
This version publication date	13 September 2023
First version publication date	13 September 2023

Trial information

Trial identification

Sponsor protocol code	CMBG453X2101
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02608268
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	30 August 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 August 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the trial were:

Phase I-Ib parts:

- To characterize the safety and tolerability of MBG453 as a single agent in rest of the world (ROW) and Japanese patients separately and in combination with PDR001 and to identify recommended doses for future studies.

- To characterize safety and tolerability of MBG453 in combination with decitabine and identify recommended dose for future studies.

Phase I-Ib dose ranging part:

- To further investigate the safety and tolerability of different doses of MBG453 as single agent or in combination with PDR001.

Phase II part:

- To estimate the anti-tumor activity of MBG453 as single agent and in combination with PDR001 or in combination with decitabine.

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	23 November 2015
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	Canada: 11
Country: Number of subjects enrolled	Italy: 50
Country: Number of subjects enrolled	Japan: 21
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Netherlands: 31
Country: Number of subjects enrolled	Singapore: 22
Country: Number of subjects enrolled	Switzerland: 28
Country: Number of subjects enrolled	Taiwan: 18
Country: Number of subjects enrolled	United States: 68
Worldwide total number of subjects	252
EEA total number of subjects	81

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)	154
From 65 to 84 years	97
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants took part in 14 investigative sites in 9 countries.

Pre-assignment

Screening details:

The screening period began once patients had signed the study informed consent. Screening evaluations were performed within 28 days prior to the first dose of study medication. After screening, the treatment period started on Cycle 1 Day 1.

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	Phase I Dose Escalation: MBG453 80mg Q2W ROW

Arm description:

Sabatolimab 80 mg every 2 weeks (Q2W) in Phase I Dose Escalation Part in rest of the world (ROW) patients

Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sabatolimab 80 mg every 2 weeks (Q2W)

Arm title	Phase I Dose Escalation: MBG453 240mg Q2W ROW
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Arm description:

Sabatolimab 240 mg Q2W in Phase I Dose Escalation Part in ROW patients

Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sabatolimab 240 mg every 2 weeks (Q2W)

Arm title	Phase I Dose Escalation: MBG453 800mg Q2W ROW
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Arm description:

Sabatolimab 800 mg Q2W in Phase I Dose Escalation Part in ROW patients

Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sabatolimab 800 mg every 2 weeks (Q2W)

Arm title	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
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Arm description:

Sabatolimab 1200 mg Q2W in Phase I Dose Escalation Part in ROW patients

Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sabatolimab 1200 mg every 2 weeks (Q2W)

Arm title	Phase I Dose Escalation: MBG453 80mg Q2W Japan
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Arm description:

Sabatolimab 80 mg Q2W in Phase I Dose Escalation Part in Japanese patients

Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sabatolimab 80 mg every 2 weeks (Q2W)

Arm title	Phase I Dose Escalation: MBG453 240mg Q2W Japan
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Arm description:

Sabatolimab 240 mg Q2W in Phase I Dose Escalation Part in Japanese patients

Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sabatolimab 240 mg every 2 weeks (Q2W)

Arm title	Phase I Dose Escalation: MBG453 800mg Q2W Japan
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Arm description:

Sabatolimab 800 mg Q2W in Phase I Dose Escalation Part in Japanese patients

Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sabatolimab 800 mg every 2 weeks (Q2W)

Arm title	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
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Arm description:	
Sabatolimab 1200 mg Q2W in Phase I Dose Escalation Part in Japanese participants	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 1200 mg every 2 weeks (Q2W)	
Arm title	Phase I Dose Escalation: MBG453 240mg Q4W ROW
Arm description:	
Sabatolimab 240 mg every 4 weeks (Q4W) in Phase I Dose Escalation Part in ROW patients	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 240 mg every 4 weeks (Q4W)	
Arm title	Phase I Dose Escalation: MBG453 800mg Q4W ROW
Arm description:	
Sabatolimab 800 mg Q4W in Phase I Dose Escalation Part in ROW patients	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 800 mg every 4 weeks (Q4W)	
Arm title	Phase I Dose Escalation: MBG453 1200mg Q4W ROW
Arm description:	
Sabatolimab 1200 mg Q4W in Phase I Dose Escalation Part in ROW patients	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 1200 mg every 4 weeks (Q4W)	
Arm title	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Arm description:	
Sabatolimab 1200 mg Q4W in Phase I Dose Escalation Part in Japanese patients	
Arm type	Experimental

Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 1200 mg every 4 weeks (Q4W)	
Arm title	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W
Arm description:	
Sabatolimab 20 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 20 mg Q2W in combination with spartalizumab 80 mg Q2W	
Arm title	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W
Arm description:	
Sabatolimab 80 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 80 mg Q2W in combination with spartalizumab 80 mg Q2W	
Arm title	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W
Arm description:	
Sabatolimab 240 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 240 mg Q2W in combination with spartalizumab 80 mg Q2W	
Arm title	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Arm description:	
Sabatolimab 240 mg Q2W in combination with spartalizumab 240 mg Q2W in Phase Ib Dose Escalation Part	
Arm type	Experimental

Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 240 mg Q2W in combination with spartalizumab 240 mg Q2W	
Arm title	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W
Arm description:	
Sabatolimab 800 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 800 mg Q2W in combination with spartalizumab 80 mg Q2W	
Arm title	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W
Arm description:	
Sabatolimab 800 mg Q2W in combination with spartalizumab 240 mg Q2W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 800 mg Q2W in combination with spartalizumab 240 mg Q2W	
Arm title	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W
Arm description:	
Sabatolimab 80 mg Q4W in combination with spartalizumab 80 mg Q4W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 80 mg Q4W in combination with spartalizumab 80 mg Q4W	
Arm title	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Arm description:	
Sabatolimab 80 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part	
Arm type	Experimental

Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 80 mg Q4W in combination with spartalizumab 400 mg Q4W	
Arm title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W
Arm description:	
Sabatolimab 240 mg Q4W in combination with spartalizumab 80 mg Q4W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 240 mg Q4W in combination with spartalizumab 80 mg Q4W	
Arm title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W
Arm description:	
Sabatolimab 240 mg Q4W in combination with spartalizumab 240 mg Q4W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 240 mg Q4W in combination with spartalizumab 240 mg Q4W	
Arm title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W
Arm description:	
Sabatolimab 240 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 240 mg Q4W in combination with spartalizumab 400 mg Q4W	
Arm title	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Arm description:	
Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part	
Arm type	Experimental

Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W	
Arm title	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W
Arm description:	
Sabatolimab 1200 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 1200 mg Q4W in combination with spartalizumab 400 mg Q4W	
Arm title	Dose Ranging Part: MBG453 80mg Q4W
Arm description:	
Sabatolimab 80 mg Q4W in Dose Ranging Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 80 mg every 4 weeks (Q4W)	
Arm title	Dose Ranging Part: MBG453 240mg Q4W
Arm description:	
Sabatolimab 240 mg Q4W in Dose Ranging Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Sabatolimab 240 mg every 4 weeks (Q4W)	
Arm title	Dose Ranging Part: MBG453 1200mg Q4W
Arm description:	
Sabatolimab 1200 mg Q4W in Dose Ranging Part	
Arm type	Experimental
Investigational medicinal product name	Sabatolimab
Investigational medicinal product code	MBG453
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
Sabatolimab 1200 mg every 4 weeks (Q4W)

Arm title	Phase II: MBG453 + PDR001 NSCLC
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Arm description:

Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W in non-small cell lung carcinoma (NSCLC)

Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W

Arm title	Phase II: MBG453 + PDR001 Melanoma
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Arm description:

Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W in melanoma

Arm type	Experimental
Investigational medicinal product name	Sabatolimab+spartalizumab
Investigational medicinal product code	MBG453+PDR001
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W

Number of subjects in period 1	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW
Started	14	9	16
Completed	0	0	0
Not completed	14	9	16
Physician decision	-	-	-
Adverse Event	-	-	1
Death	1	-	-
Progressive disease	12	8	13
Subject/guardian decision	1	1	2

Number of subjects in period 1	Phase I Dose Escalation: MBG453 1200mg Q2W ROW	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan
Started	5	2	4
Completed	0	0	0
Not completed	5	2	4

Physician decision	-	-	-
Adverse Event	-	-	-
Death	-	-	-
Progressive disease	5	2	4
Subject/guardian decision	-	-	-

Number of subjects in period 1	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q4W ROW
Started	6	2	8
Completed	0	0	0
Not completed	6	2	8
Physician decision	-	-	-
Adverse Event	-	-	-
Death	-	-	1
Progressive disease	6	2	5
Subject/guardian decision	-	-	2

Number of subjects in period 1	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Started	9	6	6
Completed	0	0	0
Not completed	9	6	6
Physician decision	-	1	-
Adverse Event	-	-	-
Death	1	-	-
Progressive disease	6	5	5
Subject/guardian decision	2	-	1

Number of subjects in period 1	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W
Started	6	13	6
Completed	0	0	0
Not completed	6	13	6
Physician decision	-	1	-
Adverse Event	2	-	-
Death	-	-	-
Progressive disease	4	11	6
Subject/guardian decision	-	1	-

Number of subjects in period 1	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W
Started	5	5	6

Completed	0	0	0
Not completed	5	5	6
Physician decision	-	-	-
Adverse Event	-	-	-
Death	1	-	1
Progressive disease	3	5	5
Subject/guardian decision	1	-	-

Number of subjects in period 1	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W
Started	6	3	12
Completed	0	0	0
Not completed	6	3	12
Physician decision	-	-	-
Adverse Event	-	-	1
Death	-	1	1
Progressive disease	5	2	10
Subject/guardian decision	1	-	-

Number of subjects in period 1	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Started	5	7	6
Completed	0	0	0
Not completed	5	7	6
Physician decision	-	1	1
Adverse Event	1	-	-
Death	-	-	-
Progressive disease	4	5	5
Subject/guardian decision	-	1	-

Number of subjects in period 1	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W
Started	6	14	17
Completed	0	0	0
Not completed	6	14	17
Physician decision	1	-	-
Adverse Event	1	-	-
Death	1	2	-
Progressive disease	3	11	16
Subject/guardian decision	-	1	1

Number of subjects in period 1	Dose Ranging Part: MBG453 1200mg Q4W	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma
Started	15	17	16
Completed	0	0	0
Not completed	15	17	16
Physician decision	2	1	1
Adverse Event	-	1	-
Death	1	4	-
Progressive disease	11	10	15
Subject/guardian decision	1	1	-

Baseline characteristics

Reporting groups

Reporting group title	Phase I Dose Escalation: MBG453 80mg Q2W ROW
Reporting group description: Sabatolimab 80 mg every 2 weeks (Q2W) in Phase I Dose Escalation Part in rest of the world (ROW) patients	
Reporting group title	Phase I Dose Escalation: MBG453 240mg Q2W ROW
Reporting group description: Sabatolimab 240 mg Q2W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 800mg Q2W ROW
Reporting group description: Sabatolimab 800 mg Q2W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Reporting group description: Sabatolimab 1200 mg Q2W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 80mg Q2W Japan
Reporting group description: Sabatolimab 80 mg Q2W in Phase I Dose Escalation Part in Japanese patients	
Reporting group title	Phase I Dose Escalation: MBG453 240mg Q2W Japan
Reporting group description: Sabatolimab 240 mg Q2W in Phase I Dose Escalation Part in Japanese patients	
Reporting group title	Phase I Dose Escalation: MBG453 800mg Q2W Japan
Reporting group description: Sabatolimab 800 mg Q2W in Phase I Dose Escalation Part in Japanese patients	
Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Reporting group description: Sabatolimab 1200 mg Q2W in Phase I Dose Escalation Part in Japanese participants	
Reporting group title	Phase I Dose Escalation: MBG453 240mg Q4W ROW
Reporting group description: Sabatolimab 240 mg every 4 weeks (Q4W) in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 800mg Q4W ROW
Reporting group description: Sabatolimab 800 mg Q4W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q4W ROW
Reporting group description: Sabatolimab 1200 mg Q4W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Reporting group description: Sabatolimab 1200 mg Q4W in Phase I Dose Escalation Part in Japanese patients	
Reporting group title	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W
Reporting group description: Sabatolimab 20 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part	
Reporting group title	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W
Reporting group description: Sabatolimab 80 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part	
Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W

Reporting group description:

Sabatolimab 240 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
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Reporting group description:

Sabatolimab 240 mg Q2W in combination with spartalizumab 240 mg Q2W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W
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Reporting group description:

Sabatolimab 800 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W
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Reporting group description:

Sabatolimab 800 mg Q2W in combination with spartalizumab 240 mg Q2W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W
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Reporting group description:

Sabatolimab 80 mg Q4W in combination with spartalizumab 80 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Sabatolimab 80 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W
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Reporting group description:

Sabatolimab 240 mg Q4W in combination with spartalizumab 80 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W
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Reporting group description:

Sabatolimab 240 mg Q4W in combination with spartalizumab 240 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Sabatolimab 240 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Sabatolimab 1200 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Dose Ranging Part: MBG453 80mg Q4W
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Reporting group description:

Sabatolimab 80 mg Q4W in Dose Ranging Part

Reporting group title	Dose Ranging Part: MBG453 240mg Q4W
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Reporting group description:

Sabatolimab 240 mg Q4W in Dose Ranging Part

Reporting group title	Dose Ranging Part: MBG453 1200mg Q4W
Reporting group description: Sabatolimab 1200 mg Q4W in Dose Ranging Part	
Reporting group title	Phase II: MBG453 + PDR001 NSCLC
Reporting group description: Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W in non-small cell lung carcinoma (NSCLC)	
Reporting group title	Phase II: MBG453 + PDR001 Melanoma
Reporting group description: Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W in melanoma	

Reporting group values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW
Number of subjects	14	9	16
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	10	6	12
From 65-84 years	4	3	4
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	59.3	50.7	53.6
standard deviation	± 13.80	± 16.69	± 15.95
Sex: Female, Male Units: participants			
Female	8	5	5
Male	6	4	11
Race/Ethnicity, Customized Units: Subjects			
Caucasian	12	9	12
Asian	1	0	3
Black	0	0	0
Unknown	0	0	1
Other	1	0	0

Reporting group values	Phase I Dose Escalation: MBG453 1200mg Q2W ROW	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan
Number of subjects	5	2	4
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0

Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	0	1
From 65-84 years	1	2	3
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	57.2	73.0	65.8
standard deviation	± 8.07	± 8.49	± 5.74
Sex: Female, Male			
Units: participants			
Female	3	1	2
Male	2	1	2
Race/Ethnicity, Customized			
Units: Subjects			
Caucasian	4	0	0
Asian	1	2	4
Black	0	0	0
Unknown	0	0	0
Other	0	0	0

Reporting group values	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q4W ROW
Number of subjects	6	2	8
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	2	6
From 65-84 years	2	0	2
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	54.0	55.0	56.1
standard deviation	± 16.64	± 7.07	± 12.76
Sex: Female, Male			
Units: participants			
Female	4	1	6
Male	2	1	2
Race/Ethnicity, Customized			
Units: Subjects			
Caucasian	0	0	7
Asian	6	2	1

Black	0	0	0
Unknown	0	0	0
Other	0	0	0

Reporting group values	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Number of subjects	9	6	6
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	3	3
From 65-84 years	4	3	3
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	62.2	60.8	63.5
standard deviation	± 10.86	± 13.09	± 7.40
Sex: Female, Male Units: participants			
Female	4	3	3
Male	5	3	3
Race/Ethnicity, Customized Units: Subjects			
Caucasian	9	5	0
Asian	0	1	6
Black	0	0	0
Unknown	0	0	0
Other	0	0	0

Reporting group values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W
Number of subjects	6	13	6
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	8	5
From 65-84 years	2	5	1
85 years and over	0	0	0

Age Continuous Units: years arithmetic mean standard deviation	47.8 ± 13.92	56.9 ± 13.98	56.5 ± 16.56
Sex: Female, Male Units: participants			
Female	2	7	2
Male	4	6	4
Race/Ethnicity, Customized Units: Subjects			
Caucasian	2	11	4
Asian	3	2	2
Black	1	0	0
Unknown	0	0	0
Other	0	0	0

Reporting group values	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W
Number of subjects	5	5	6
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	3	4
From 65-84 years	2	2	2
85 years and over	0	0	0
Age Continuous Units: years arithmetic mean standard deviation	54.6 ± 15.87	56.0 ± 10.58	54.0 ± 12.77
Sex: Female, Male Units: participants			
Female	2	0	4
Male	3	5	2
Race/Ethnicity, Customized Units: Subjects			
Caucasian	4	2	4
Asian	1	3	1
Black	0	0	1
Unknown	0	0	0
Other	0	0	0

Reporting group values	Phase Ib Dose Escalation: MBG453 80mg Q4W +	Phase Ib Dose Escalation: MBG453 80mg Q4W +	Phase Ib Dose Escalation: MBG453 240mg Q4W +
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	PDR001 80mg Q4W	PDR001 400mg Q4W	PDR001 80mg Q4W
Number of subjects	6	3	12
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	1	4
From 65-84 years	2	2	8
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	54.2	62.3	66.0
standard deviation	± 14.47	± 22.37	± 7.02
Sex: Female, Male			
Units: participants			
Female	3	2	5
Male	3	1	7
Race/Ethnicity, Customized			
Units: Subjects			
Caucasian	3	2	10
Asian	3	1	2
Black	0	0	0
Unknown	0	0	0
Other	0	0	0

Reporting group values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Number of subjects	5	7	6
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	4	5
From 65-84 years	1	3	1
85 years and over	1	0	0
Age Continuous			
Units: years			
arithmetic mean	59.4	61.3	53.8
standard deviation	± 20.16	± 14.51	± 10.36

Sex: Female, Male			
Units: participants			
Female	2	3	4
Male	3	4	2
Race/Ethnicity, Customized			
Units: Subjects			
Caucasian	4	5	3
Asian	1	2	2
Black	0	0	0
Unknown	0	0	0
Other	0	0	1

Reporting group values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W
Number of subjects	6	14	17
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	10	11
From 65-84 years	3	4	6
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	57.7	57.4	59.4
standard deviation	± 12.16	± 12.20	± 10.12
Sex: Female, Male			
Units: participants			
Female	3	10	14
Male	3	4	3
Race/Ethnicity, Customized			
Units: Subjects			
Caucasian	5	12	15
Asian	1	1	1
Black	0	1	0
Unknown	0	0	1
Other	0	0	0

Reporting group values	Dose Ranging Part: MBG453 1200mg Q4W	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma
Number of subjects	15	17	16
Age categorical			
Units: Subjects			
In utero	0	0	0

Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	11	7	8
From 65-84 years	4	10	8
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	57.3	64.5	61.8
standard deviation	± 11.85	± 10.28	± 11.35
Sex: Female, Male Units: participants			
Female	13	3	8
Male	2	14	8
Race/Ethnicity, Customized Units: Subjects			
Caucasian	14	11	8
Asian	0	5	8
Black	1	0	0
Unknown	0	0	0
Other	0	1	0

Reporting group values	Total		
Number of subjects	252		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	154		
From 65-84 years	97		
85 years and over	1		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: participants			
Female	132		
Male	120		
Race/Ethnicity, Customized Units: Subjects			
Caucasian	177		
Asian	66		

Black	4		
Unknown	2		
Other	3		

End points

End points reporting groups

Reporting group title	Phase I Dose Escalation: MBG453 80mg Q2W ROW
Reporting group description: Sabalolimab 80 mg every 2 weeks (Q2W) in Phase I Dose Escalation Part in rest of the world (ROW) patients	
Reporting group title	Phase I Dose Escalation: MBG453 240mg Q2W ROW
Reporting group description: Sabalolimab 240 mg Q2W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 800mg Q2W ROW
Reporting group description: Sabalolimab 800 mg Q2W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Reporting group description: Sabalolimab 1200 mg Q2W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 80mg Q2W Japan
Reporting group description: Sabalolimab 80 mg Q2W in Phase I Dose Escalation Part in Japanese patients	
Reporting group title	Phase I Dose Escalation: MBG453 240mg Q2W Japan
Reporting group description: Sabalolimab 240 mg Q2W in Phase I Dose Escalation Part in Japanese patients	
Reporting group title	Phase I Dose Escalation: MBG453 800mg Q2W Japan
Reporting group description: Sabalolimab 800 mg Q2W in Phase I Dose Escalation Part in Japanese patients	
Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Reporting group description: Sabalolimab 1200 mg Q2W in Phase I Dose Escalation Part in Japanese participants	
Reporting group title	Phase I Dose Escalation: MBG453 240mg Q4W ROW
Reporting group description: Sabalolimab 240 mg every 4 weeks (Q4W) in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 800mg Q4W ROW
Reporting group description: Sabalolimab 800 mg Q4W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q4W ROW
Reporting group description: Sabalolimab 1200 mg Q4W in Phase I Dose Escalation Part in ROW patients	
Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Reporting group description: Sabalolimab 1200 mg Q4W in Phase I Dose Escalation Part in Japanese patients	
Reporting group title	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W
Reporting group description: Sabalolimab 20 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part	
Reporting group title	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W
Reporting group description: Sabalolimab 80 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part	
Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W

Reporting group description:

Sabatolimab 240 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
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Reporting group description:

Sabatolimab 240 mg Q2W in combination with spartalizumab 240 mg Q2W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W
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Reporting group description:

Sabatolimab 800 mg Q2W in combination with spartalizumab 80 mg Q2W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W
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Reporting group description:

Sabatolimab 800 mg Q2W in combination with spartalizumab 240 mg Q2W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W
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Reporting group description:

Sabatolimab 80 mg Q4W in combination with spartalizumab 80 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Sabatolimab 80 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W
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Reporting group description:

Sabatolimab 240 mg Q4W in combination with spartalizumab 80 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W
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Reporting group description:

Sabatolimab 240 mg Q4W in combination with spartalizumab 240 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Sabatolimab 240 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Sabatolimab 1200 mg Q4W in combination with spartalizumab 400 mg Q4W in Phase Ib Dose Escalation Part

Reporting group title	Dose Ranging Part: MBG453 80mg Q4W
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Reporting group description:

Sabatolimab 80 mg Q4W in Dose Ranging Part

Reporting group title	Dose Ranging Part: MBG453 240mg Q4W
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Reporting group description:

Sabatolimab 240 mg Q4W in Dose Ranging Part

Reporting group title	Dose Ranging Part: MBG453 1200mg Q4W
Reporting group description: Sabatolimab 1200 mg Q4W in Dose Ranging Part	
Reporting group title	Phase II: MBG453 + PDR001 NSCLC
Reporting group description: Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W in non-small cell lung carcinoma (NSCLC)	
Reporting group title	Phase II: MBG453 + PDR001 Melanoma
Reporting group description: Sabatolimab 800 mg Q4W in combination with spartalizumab 400 mg Q4W in melanoma	

Primary: Phase I-Ib and Dose Ranging Part: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

End point title	Phase I-Ib and Dose Ranging Part: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period ^{[1][2]}
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End point description:

Number of participants with AEs and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs.

AE grades to characterize the severity of the AEs were based on the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. For CTCAE v4.03, Grade 1 = mild; Grade 2 = moderate; Grade 3 = severe; Grade 4 = life-threatening; Grade 5 = death related to AE.

The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.

End point type	Primary
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End point timeframe:

From first dose of study medication up to 30 days after last dose, with a maximum duration of 2 years for sabatolimab and 5 years for sabatolimab in combination with spartalizumab

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis were planned for this endpoint.

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

Justification: This endpoint only applies to Phase I-Ib and Dose Ranging Part

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	16	5
Units: participants				
AEs	13	9	14	5
Treatment-related AEs	9	5	6	1
AEs with grade ≥ 3	5	3	6	2
Treatment-related AEs with grade ≥ 3	0	0	0	0
SAEs	4	1	6	2
Fatal SAEs	2	0	0	1
AEs leading to discontinuation	0	0	1	0
AEs leading to dose adjustment/interruption	3	0	3	0
AEs requiring additional therapy	13	4	12	4

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	6	2
Units: participants				
AEs	2	3	6	2
Treatment-related AEs	0	0	1	0
AEs with grade ≥ 3	0	1	2	0
Treatment-related AEs with grade ≥ 3	0	0	0	0
SAEs	0	0	0	0
Fatal SAEs	0	0	0	0
AEs leading to discontinuation	0	0	0	0
AEs leading to dose adjustment/interruption	0	1	1	1
AEs requiring additional therapy	2	3	6	2

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	6	6
Units: participants				
AEs	7	9	6	5
Treatment-related AEs	4	6	2	1
AEs with grade ≥ 3	3	7	4	3
Treatment-related AEs with grade ≥ 3	0	0	0	0
SAEs	1	5	4	0
Fatal SAEs	0	0	0	0
AEs leading to discontinuation	0	1	0	0
AEs leading to dose adjustment/interruption	1	2	0	1
AEs requiring additional therapy	7	7	3	3

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: participants				

AEs	6	12	6	5
Treatment-related AEs	5	7	5	4
AEs with grade ≥ 3	4	9	3	5
Treatment-related AEs with grade ≥ 3	2	1	0	1
SAEs	2	6	2	4
Fatal SAEs	1	1	1	3
AEs leading to discontinuation	2	0	0	0
AEs leading to dose adjustment/interruption	3	3	3	1
AEs requiring additional therapy	5	12	4	5

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: participants				
AEs	5	6	6	3
Treatment-related AEs	2	4	3	1
AEs with grade ≥ 3	3	0	4	1
Treatment-related AEs with grade ≥ 3	0	0	1	0
SAEs	4	0	4	1
Fatal SAEs	0	0	0	0
AEs leading to discontinuation	0	0	0	0
AEs leading to dose adjustment/interruption	3	1	1	1
AEs requiring additional therapy	4	4	6	3

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: participants				
AEs	11	5	7	6
Treatment-related AEs	5	5	3	4
AEs with grade ≥ 3	3	3	6	5
Treatment-related AEs with grade ≥ 3	2	0	1	1
SAEs	2	3	1	3
Fatal SAEs	0	0	0	0
AEs leading to discontinuation	1	1	0	0
AEs leading to dose adjustment/interruption	1	0	1	2
AEs requiring additional therapy	10	5	3	6

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	14	17	15
Units: participants				
AEs	6	13	17	14
Treatment-related AEs	2	3	7	10
AEs with grade ≥ 3	4	10	7	10
Treatment-related AEs with grade ≥ 3	0	1	1	2
SAEs	3	8	7	7
Fatal SAEs	0	1	0	0
AEs leading to discontinuation	1	1	1	0
AEs leading to dose adjustment/interruption	2	1	0	2
AEs requiring additional therapy	5	12	17	12

Statistical analyses

No statistical analyses for this end point

Primary: Phase I-Ib: Number of participants with Dose-Limiting Toxicities (DLTs)

End point title	Phase I-Ib: Number of participants with Dose-Limiting Toxicities (DLTs) ^{[3][4]}
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End point description:

A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as unrelated to disease, disease progression, inter-current illness or concomitant medications, which occurs within the first cycle of treatment with sabatolimab as single agent or in the first two cycles of treatment when sabatolimab is given in combination with spartalizumab during the dose escalation part of the study. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher. The duration of one treatment cycle is 28 days.

End point type	Primary
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End point timeframe:

28 days (sabatolimab single agent) and 56 days (sabatolimab+spartalizumab)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis were planned for this endpoint.

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

Justification: This endpoint only applies to Phase I-Ib

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	9	12	5
Units: participants	0	0	0	0

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	6	2
Units: participants	0	0	0	0

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	5	6
Units: participants	0	0	0	0

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	12	4	4
Units: participants	0	0	0	0

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	6	2
Units: participants	0	0	0	0

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	5	4
Units: participants	1	0	0	0

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: Phase I-Ib and Dose Ranging Part: Number of participants with dose reductions and dose interruptions of sabatolimab

End point title	Phase I-Ib and Dose Ranging Part: Number of participants with dose reductions and dose interruptions of sabatolimab ^[5] ^[6]
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End point description:

Number of participants with at least one dose reduction of sabatolimab and number of participants with at least one dose interruption of sabatolimab.

End point type	Primary
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End point timeframe:

From first dose of study medication up to last dose, with a maximum duration of 1.9 years for sabatolimab and 4.9 years for sabatolimab in combination with spartalizumab

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: No statistical analysis were planned for this endpoint.

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

Justification: This endpoint only applies to Phase I-Ib and Dose Ranging Part

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	16	5
Units: participants				
At least one dose reduction	0	0	2	0
At least one dose interruption	2	1	3	0

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	6	2
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	0	2	1	0

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	6	6
Units: participants				
At least one dose reduction	0	1	0	0
At least one dose interruption	0	1	0	0

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	2	2	1	1

End point values	Phase Ib Dose	Phase Ib Dose	Phase Ib Dose	Phase Ib Dose
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	Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	2	1	1	0

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	0	0	2	1

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	14	17	15
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	1	1	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Phase Ib: Number of participants with dose reductions and dose interruptions of spartalizumab

End point title	Phase Ib: Number of participants with dose reductions and dose interruptions of spartalizumab ^{[7][8]}
End point description:	
Number of participants with at least one dose reduction of spartalizumab and number of participants with at least one dose interruption of spartalizumab.	
End point type	Primary
End point timeframe:	
From first dose of study medication up to last dose, with a maximum duration of 4.9 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: No statistical analysis were planned for this endpoint.

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

Justification: This endpoint only applies to Phase Ib

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: participants				
At least one dose reduction	0	1	0	0
At least one dose interruption	2	2	1	1

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	2	1	1	0

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	0	0	2	1

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W			
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Subject group type	Reporting group			
Number of subjects analysed	6			
Units: participants				
At least one dose reduction	0			
At least one dose interruption	1			

Statistical analyses

No statistical analyses for this end point

Primary: Phase I-Ib and Dose Ranging Part: Dose intensity of sabatolimab

End point title	Phase I-Ib and Dose Ranging Part: Dose intensity of sabatolimab ^{[9][10]}
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End point description:

Dose intensity of sabatolimab Q2W was calculated as cumulative actual dose in milligrams divided by duration of exposure in days and then multiplied by 14 days.

Dose intensity of sabatolimab Q4W was calculated as cumulative actual dose in milligrams divided by duration of exposure in days and then multiplied by 28 days.

End point type	Primary
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End point timeframe:

From first dose of study medication up to last dose, with a maximum duration of 1.9 years for sabatolimab and 4.9 years for sabatolimab in combination with spartalizumab

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: No statistical analysis were planned for this endpoint.

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

Justification: This endpoint only applies to Phase I-Ib and Dose Ranging Part

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	16	5
Units: milligrams				
arithmetic mean (standard deviation)	78.35 (± 4.678)	235.60 (± 17.140)	728.06 (± 164.525)	1203.03 (± 15.891)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	6	2
Units: milligrams				
arithmetic mean (standard deviation)	80.00 (± 0.000)	217.50 (± 28.723)	758.03 (± 57.03)	1208.70 (± 12.298)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	6	6
Units: milligrams				
arithmetic mean (standard deviation)	240.19 (± 1.954)	752.29 (± 123.021)	1193.10 (± 16.893)	1196.49 (± 8.595)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: milligrams				
arithmetic mean (standard deviation)	19.34 (± 1.043)	78.58 (± 2.872)	236.19 (± 15.050)	230.24 (± 19.982)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: milligrams				
arithmetic mean (standard deviation)	743.88 (± 79.534)	763.72 (± 89.571)	76.39 (± 5.315)	80.11 (± 0.184)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: milligrams				
arithmetic mean (standard deviation)	239.36 (± 4.227)	236.00 (± 7.800)	230.28 (± 21.179)	755.79 (± 103.897)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	14	17	15
Units: milligrams				
arithmetic mean (standard deviation)	1196.15 (± 9.421)	79.55 (± 1.661)	239.68 (± 4.977)	1192.33 (± 23.366)

Statistical analyses

No statistical analyses for this end point

Primary: Phase Ib: Dose intensity of spartalizumab

End point title	Phase Ib: Dose intensity of spartalizumab ^{[11][12]}
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End point description:

Dose intensity of spartalizumab Q2W was calculated as cumulative actual dose in milligrams divided by duration of exposure in days and then multiplied by 14 days.

Dose intensity of spartalizumab Q4W was calculated as cumulative actual dose in milligrams divided by duration of exposure in days and then multiplied by 28 days.

End point type	Primary
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End point timeframe:

From first dose of study medication up to last dose, with a maximum duration of 4.9 years

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: No statistical analysis were planned for this endpoint.

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

Justification: This endpoint only applies to Phase Ib

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: milligrams				
arithmetic mean (standard deviation)	77.36 (± 4.171)	77.83 (± 3.957)	78.73 (± 5.017)	230.24 (± 19.982)

End point values	Phase Ib Dose Escalation:	Phase Ib Dose Escalation:	Phase Ib Dose Escalation:	Phase Ib Dose Escalation:
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	MBG453 800mg Q2W + PDR001 80mg Q2W	MBG453 800mg Q2W + PDR001 240mg Q2W	MBG453 80mg Q4W + PDR001 80mg Q4W	MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: milligrams				
arithmetic mean (standard deviation)	74.39 (± 7.953)	229.12 (± 26.871)	76.39 (± 5.315)	400.53 (± 0.920)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: milligrams				
arithmetic mean (standard deviation)	79.79 (± 1.409)	236.00 (± 7.800)	383.22 (± 36.754)	377.89 (± 51.948)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: milligrams				
arithmetic mean (standard deviation)	398.72 (± 3.140)			

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 ^{[13][14]}
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End point description:

Tumor response was based on local investigator assessment as per Response Evaluation Criteria In Solid Tumors (RECIST) v1.1. ORR per RECIST v1.1 is defined as the percentage of participants with a best overall response of Complete Response (CR) or Partial Response (PR).

For RECIST v1.1, CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.

End point type	Primary
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End point timeframe:

From start of treatment until end of treatment, assessed up to 2.9 years

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: No statistical analysis were planned for this endpoint.

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

Justification: This endpoint only applies to Phase II

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.0 to 16.2)	0 (0.0 to 17.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR) per RECIST v1.1

End point title	Best Overall Response (BOR) per RECIST v1.1
End point description:	
BOR is defined as the best response recorded from the start of the study treatment until disease progression/recurrence, based on local investigator assessment per RECIST v1.1. For RECIST v1.1, CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameters of all target lesions, taking as reference the baseline sum of diameters; PD= At least a 20% increase in the sum of diameters of all measured target lesions, taking as reference the smallest sum of diameter of all target lesions recorded at or after baseline. In addition, the sum must also demonstrate an absolute increase of at least 5 mm; SD= Neither sufficient shrinkage to qualify for PR or CR nor an increase in lesions which would qualify for progression; NCRNPD: Persistence of one or more non-target lesions. Number of participants in each category is reported in the table.	
End point type	Secondary
End point timeframe:	
From start of treatment until end of treatment, assessed up to 1.9 years for sabatolimab and 4.9 years for sabatolimab in combination with spartalizumab	

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	16	5
Units: participants				
Complete Response (CR)	0	0	0	0
Partial Response (PR)	0	0	0	0
Stable Disease (SD)	4	3	7	0

Progressive Disease (PD)	7	6	8	5
Non-CR/Non-PD (NCRNPD)	0	0	0	0
Unknown	3	0	1	0

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	6	2
Units: participants				
Complete Response (CR)	0	0	0	0
Partial Response (PR)	0	0	0	0
Stable Disease (SD)	0	1	2	0
Progressive Disease (PD)	2	3	4	2
Non-CR/Non-PD (NCRNPD)	0	0	0	0
Unknown	0	0	0	0

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	6	6
Units: participants				
Complete Response (CR)	0	0	0	0
Partial Response (PR)	0	0	0	0
Stable Disease (SD)	3	1	0	3
Progressive Disease (PD)	3	4	4	3
Non-CR/Non-PD (NCRNPD)	1	0	0	0
Unknown	1	4	2	0

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: participants				
Complete Response (CR)	0	0	0	0
Partial Response (PR)	1	1	0	0
Stable Disease (SD)	4	7	2	1
Progressive Disease (PD)	1	4	4	4
Non-CR/Non-PD (NCRNPD)	0	0	0	0

Unknown	0	1	0	0
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End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: participants				
Complete Response (CR)	0	0	0	0
Partial Response (PR)	0	0	0	0
Stable Disease (SD)	1	1	3	1
Progressive Disease (PD)	3	4	3	1
Non-CR/Non-PD (NCRNPD)	0	0	0	0
Unknown	1	1	0	1

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: participants				
Complete Response (CR)	0	0	0	0
Partial Response (PR)	0	0	2	1
Stable Disease (SD)	5	3	2	2
Progressive Disease (PD)	7	2	1	3
Non-CR/Non-PD (NCRNPD)	0	0	0	0
Unknown	0	0	2	0

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	14	17	15
Units: participants				
Complete Response (CR)	0	0	0	0
Partial Response (PR)	0	0	0	0
Stable Disease (SD)	1	4	2	4
Progressive Disease (PD)	3	7	13	8
Non-CR/Non-PD (NCRNPD)	0	0	0	0

Unknown	2	3	2	3
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End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: participants				
Complete Response (CR)	0	0		
Partial Response (PR)	0	0		
Stable Disease (SD)	6	3		
Progressive Disease (PD)	5	12		
Non-CR/Non-PD (NCRNPD)	0	0		
Unknown	6	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) per RECIST v1.1

End point title	Progression-Free Survival (PFS) per RECIST v1.1
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End point description:

PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause. If a patient did not have an event, PFS was censored at the date of the last adequate tumor assessment. Tumor response was based on local investigator assessment per RECIST v1.1.

PFS was analyzed using Kaplan-Meier estimates.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary
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End point timeframe:

From start of treatment until first documented progression or death due to any cause, assessed up to 1.9 years for sabatolimab and 4.9 years for sabatolimab in combination with spartalizumab

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	16	5
Units: months				
median (confidence interval 90%)	1.8 (1.7 to 3.3)	1.8 (1.6 to 2.8)	1.8 (1.7 to 5.3)	1.7 (1.3 to 999)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	6	2
Units: months				
median (confidence interval 90%)	1.5 (1.4 to 999)	1.9 (1.0 to 999)	2.0 (1.0 to 3.3)	1.6 (1.4 to 999)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	6	6
Units: months				
median (confidence interval 90%)	1.7 (1.0 to 999)	1.7 (0.7 to 1.8)	1.8 (1.6 to 999)	2.0 (1.1 to 3.5)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: months				
median (confidence interval 90%)	3.6 (1.8 to 999)	3.6 (1.8 to 3.7)	1.7 (1.0 to 3.7)	1.8 (1.0 to 999)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: months				
median (confidence interval 90%)	1.8 (1.7 to 999)	1.7 (0.5 to 1.8)	2.6 (1.6 to 3.7)	2.4 (1.8 to 999)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: months				
median (confidence interval 90%)	1.8 (1.7 to 3.0)	3.5 (1.8 to 999)	999 (1.5 to 999)	2.7 (1.1 to 3.8)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	14	17	15
Units: months				
median (confidence interval 90%)	1.7 (0.2 to 2.4)	1.8 (1.7 to 3.7)	1.7 (1.6 to 1.8)	1.7 (1.7 to 2.1)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: months				
median (confidence interval 90%)	1.7 (1.1 to 3.4)	1.8 (1.7 to 1.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) per RECIST v1.1

End point title	Duration of Response (DOR) per RECIST v1.1
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End point description:

DOR only applies to patients for whom best overall response is complete response (CR) or partial response (PR) based on local investigator assessment according to RECIST v1.1. DOR is defined as the time from the date of first documented response to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, duration was censored at the date of last adequate tumor assessment.

According to the statistical analysis plan (SAP), summary estimates of DOR using the Kaplan-Meier method were planned to be reported if there were at least 10 patients achieving a confirmed CR or PR in

each treatment group/arm.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA). Therefore, not available values because of insufficient number of responders as per SAP are indicated as '999'.

End point type	Secondary
End point timeframe:	
From first documented response to first documented disease progression or death due to underlying cancer, assessed up to 1.9 years for sabatolimab and 4.9 years for sabatolimab in combination with spartalizumab	

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[15]	0 ^[16]	0 ^[17]	0 ^[18]
Units: months				
median (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[15] - No patients with CR or PR

[16] - No patients with CR or PR

[17] - No patients with CR or PR

[18] - No patients with CR or PR

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[19]	0 ^[20]	0 ^[21]	0 ^[22]
Units: months				
median (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[19] - No patients with CR or PR

[20] - No patients with CR or PR

[21] - No patients with CR or PR

[22] - No patients with CR or PR

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[23]	0 ^[24]	0 ^[25]	0 ^[26]
Units: months				
median (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[23] - No patients with CR or PR

[24] - No patients with CR or PR

[25] - No patients with CR or PR

[26] - No patients with CR or PR

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	0 ^[27]	0 ^[28]
Units: months				
median (confidence interval 90%)	999 (999 to 999)	999 (999 to 999)	(to)	(to)

Notes:

[27] - No patients with CR or PR

[28] - No patients with CR or PR

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[29]	0 ^[30]	0 ^[31]	0 ^[32]
Units: months				
median (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[29] - No patients with CR or PR

[30] - No patients with CR or PR

[31] - No patients with CR or PR

[32] - No patients with CR or PR

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[33]	0 ^[34]	2	1
Units: months				
median (confidence interval 90%)	(to)	(to)	999 (999 to 999)	999 (999 to 999)

Notes:

[33] - No patients with CR or PR

[34] - No patients with CR or PR

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[35]	0 ^[36]	0 ^[37]	0 ^[38]
Units: months				
median (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

- [35] - No patients with CR or PR
- [36] - No patients with CR or PR
- [37] - No patients with CR or PR
- [38] - No patients with CR or PR

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[39]	0 ^[40]		
Units: months				
median (confidence interval 90%)	(to)	(to)		

Notes:

- [39] - No patients with CR or PR
- [40] - No patients with CR or PR

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) per irRC

End point title	Overall Response Rate (ORR) per irRC
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End point description:

Tumor response was based on local investigator assessment as per irRC. ORR per irRC is defined as the percentage of participants with a best overall response of immune related Complete Response (irCR) or immune related Partial Response (irPR).

For irRC, irCR=Disappearance of all non-nodal target lesions and non-target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; irPR= At least a 30% decrease in the sum of diameters of all target lesions including new measurable lesions, taking as reference the baseline sum of diameters.

End point type	Secondary
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End point timeframe:

From start of treatment until end of treatment, assessed up to 1.9 years for sabatolimab and 4.9 years for sabatolimab in combination with spartalizumab

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	16	5
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.0 to 19.3)	0 (0.0 to 28.3)	0 (0.0 to 17.1)	0 (0.0 to 45.1)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	6	2
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.0 to 77.6)	0 (0.0 to 52.7)	0 (0.0 to 39.3)	0 (0.0 to 77.6)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	6	6
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.0 to 31.2)	0 (0.0 to 28.3)	0 (0.0 to 39.3)	0 (0.0 to 39.3)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: Percentage of participants				
number (confidence interval 90%)	16.7 (0.9 to 58.2)	7.7 (0.4 to 31.6)	0 (0.0 to 39.3)	0 (0.0 to 45.1)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.0 to 45.1)	0 (0.0 to 39.3)	0 (0.0 to 39.3)	0 (0.0 to 63.2)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: Percentage of participants				

number (confidence interval 90%)	0 (0.0 to 22.1)	0 (0.0 to 45.1)	28.6 (5.3 to 65.9)	16.7 (0.9 to 58.2)
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End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	14	17	15
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.0 to 39.3)	0 (0.0 to 19.3)	0 (0.0 to 16.2)	0 (0.0 to 18.1)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.0 to 16.2)	0 (0.0 to 17.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) per irRC

End point title	Progression-Free Survival (PFS) per irRC
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End point description:

PFS is defined as the time from the date of start of treatment to the date of the first documented and confirmed progression or death due to any cause. If a patient did not have an event, PFS was censored at the date of the last adequate tumor evaluation. Tumor response was based on local investigator assessment per irRC.

PFS was analyzed using Kaplan-Meier estimates.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary
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End point timeframe:

From start of treatment until first documented and confirmed progression or death due to any cause, assessed up to 1.9 years for sabatolimab and 4.9 years for sabatolimab in combination with spartalizumab

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	16	5
Units: months				
median (confidence interval 90%)	1.8 (1.7 to 3.3)	1.8 (1.6 to 3.0)	1.8 (1.7 to 5.3)	1.7 (1.3 to 999)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	6	2
Units: months				
median (confidence interval 90%)	1.5 (1.4 to 999)	1.9 (1.0 to 999)	2.0 (1.0 to 3.3)	1.6 (1.4 to 999)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	6	6
Units: months				
median (confidence interval 90%)	1.7 (1.0 to 999)	1.8 (0.7 to 2.5)	2.3 (1.8 to 999)	2.0 (1.1 to 3.5)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: months				
median (confidence interval 90%)	3.6 (1.8 to 999)	3.6 (1.8 to 3.7)	1.7 (1.0 to 3.7)	1.8 (1.0 to 999)

End point values	Phase Ib Dose Escalation: MBG453	Phase Ib Dose Escalation: MBG453	Phase Ib Dose Escalation: MBG453 80mg	Phase Ib Dose Escalation: MBG453 80mg
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	800mg Q2W + PDR001 80mg Q2W	800mg Q2W + PDR001 240mg Q2W	Q4W + PDR001 80mg Q4W	Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: months				
median (confidence interval 90%)	1.8 (1.7 to 999)	1.7 (0.5 to 1.8)	2.6 (1.6 to 3.7)	2.4 (1.8 to 999)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: months				
median (confidence interval 90%)	2.3 (1.7 to 3.6)	5.5 (3.5 to 999)	999 (1.5 to 999)	2.7 (1.1 to 3.8)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	14	17	15
Units: months				
median (confidence interval 90%)	1.7 (0.2 to 2.4)	1.8 (1.7 to 3.2)	1.7 (1.6 to 1.8)	1.7 (1.7 to 2.1)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: months				
median (confidence interval 90%)	1.7 (1.1 to 3.4)	1.8 (1.7 to 1.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
End point description:	
OS is defined as the time from date of start of treatment to date of death due to any cause. If a patient was not known to have died, survival was censored at the date of last known date patient alive. OS was estimated using Kaplan-Meier estimates. Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.	
End point type	Secondary
End point timeframe:	
From start of treatment until death due to any cause, assessed up to 2 years for sabatolimab and 5.3 years for sabatolimab in combination with spartalizumab	

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	16	5
Units: months				
median (confidence interval 90%)	4.1 (2.4 to 7.7)	6.7 (4.6 to 9.2)	10.3 (4.9 to 15.9)	4.3 (1.4 to 999)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	6	2
Units: months				
median (confidence interval 90%)	4.1 (1.8 to 999)	4.2 (2.3 to 999)	5.0 (1.7 to 7.5)	8.5 (3.1 to 999)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	6	6
Units: months				
median (confidence interval 90%)	12.5 (1.8 to 999)	2.5 (1.6 to 11.1)	4.8 (2.8 to 999)	6.6 (1.9 to 11.5)

End point values	Phase Ib Dose	Phase Ib Dose	Phase Ib Dose	Phase Ib Dose
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	Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	13	6	5
Units: months				
median (confidence interval 90%)	24.4 (3.4 to 999)	10.0 (6.2 to 41.8)	9.6 (1.5 to 999)	3.1 (1.2 to 999)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	3
Units: months				
median (confidence interval 90%)	20.6 (2.0 to 999)	5.4 (0.5 to 999)	999 (8.1 to 999)	3.6 (2.4 to 999)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	5	7	6
Units: months				
median (confidence interval 90%)	8.6 (4.9 to 18.3)	12.3 (3.7 to 999)	24.8 (1.5 to 999)	18.0 (1.4 to 999)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	14	17	15
Units: months				
median (confidence interval 90%)	2.4 (0.2 to 6.8)	4.0 (1.8 to 13.8)	4.9 (3.4 to 11.2)	10.9 (2.2 to 14.6)

End point values	Phase II:	Phase II:		
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	MBG453 + PDR001 NSCLC	MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: months				
median (confidence interval 90%)	6.6 (1.1 to 9.0)	6.7 (5.2 to 13.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum observed serum concentration (Cmax) of sabatolimab

End point title	Maximum observed serum concentration (Cmax) of sabatolimab
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End point description:

Pharmacokinetic (PK) parameters were calculated based on sabatolimab serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed serum concentration following a dose.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
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End point timeframe:

pre-infusion and 1, 24, 168, 240 and 336 hours after completion of the sabatolimab infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. The duration of one cycle was 28 days.

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14 ^[41]	9 ^[42]	16 ^[43]	5 ^[44]
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	23 (± 6.28)	81.3 (± 24.4)	251 (± 57.3)	429 (± 152)
Cycle 3	24.8 (± 13.5)	144 (± 60.8)	420 (± 138)	563 (± 999)

Notes:

[41] - n=14 (Cycle 1), 8 (Cycle 3)

[42] - n=9 (Cycle 1), 5 (Cycle 3)

[43] - n=16 (Cycle 1), 10 (Cycle 3)

[44] - n=5 (Cycle 1), 1 (Cycle 3)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[45]	4 ^[46]	6 ^[47]	2 ^[48]

Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	36.1 (± 0.919)	74 (± 8.59)	321 (± 64.2)	443 (± 4.24)
Cycle 3	999 (± 999)	999 (± 999)	443 (± 190)	709 (± 999)

Notes:

[45] - n=2 (Cycle 1), 0 (Cycle 3)

[46] - n=4 (Cycle 1), 0 (Cycle 3)

[47] - n=6 (Cycle 1), 3 (Cycle 3)

[48] - n=2 (Cycle 1), 1 (Cycle 3)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[49]	9 ^[50]	6 ^[51]	6 ^[52]
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	98.8 (± 50.8)	271 (± 78.5)	304 (± 86.5)	457 (± 135)
Cycle 3	116 (± 28.6)	333 (± 39.6)	448 (± 999)	713 (± 14.8)

Notes:

[49] - n=8 (Cycle 1), 2 (Cycle 3)

[50] - n= 9 (Cycle 1), 2 (Cycle 3)

[51] - n=6 (Cycle 1), 1 (Cycle 3)

[52] - n=6 (Cycle 1), 2 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[53]	13 ^[54]	6 ^[55]	4 ^[56]
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	7.68 (± 3.68)	23 (± 6.38)	83 (± 20.7)	58.3 (± 12.7)
Cycle 3	12.7 (± 16.8)	40.2 (± 31.1)	101 (± 25.6)	45.4 (± 999)

Notes:

[53] - n=6 (Cycle 1), 6 (Cycle 3)

[54] - n=13 (Cycle 1), 8 (Cycle 3)

[55] - n=6 (Cycle 1), 3 (Cycle 3)

[56] - n=4 (Cycle 1), 1 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[57]	6 ^[58]	6 ^[59]	3 ^[60]
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	213 (± 4.19)	189 (± 70.6)	22.9 (± 5.91)	23.3 (± 0.529)

Cycle 3	379 (± 104)	422 (± 49.5)	25.8 (± 5.22)	18.6 (± 0.99)
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Notes:

[57] - n=4 (Cycle 1), 3 (Cycle 3)

[58] - n=6 (Cycle 1), 2 (Cycle 3)

[59] - n=6 (Cycle 1), 4 (Cycle 3)

[60] - n=3 (Cycle 1), 2 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12 ^[61]	5 ^[62]	6 ^[63]	6 ^[64]
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	72 (± 18.3)	59.7 (± 30.2)	79 (± 26)	254 (± 38.7)
Cycle 3	77 (± 27.2)	104 (± 32.5)	102 (± 32.5)	286 (± 60.8)

Notes:

[61] - n=12 (Cycle 1), 8 (Cycle 3)

[62] - n=5 (Cycle 1), 4 (Cycle 3)

[63] - n=6 (Cycle 1), 5 (Cycle 3)

[64] - n=6 (Cycle 1), 4 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[65]	14 ^[66]	17 ^[67]	15 ^[68]
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	343 (± 112)	34.6 (± 21.8)	86.2 (± 27)	394 (± 86.7)
Cycle 3	557 (± 999)	31.2 (± 5.58)	94.4 (± 19.1)	412 (± 124)

Notes:

[65] - n=5 (Cycle 1), 1 (Cycle 3)

[66] - n=14 (Cycle 1), 6 (Cycle 3)

[67] - n=17 (Cycle 1), 5 (Cycle 3)

[68] - n=15 (Cycle 1), 4 (Cycle 3)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17 ^[69]	16 ^[70]		
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	185 (± 64.6)	233 (± 60.3)		
Cycle 3	267 (± 82.5)	316 (± 105)		

Notes:

[69] - n=17 (Cycle 1), 8 (Cycle 3)

[70] - n=16 (Cycle 1), 9 (Cycle 3)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to reach maximum serum concentration (Tmax) of sabatolimab

End point title	Time to reach maximum serum concentration (Tmax) of sabatolimab
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End point description:

PK parameters were calculated based on sabatolimab serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) serum concentration following a dose. Actual recorded sampling times were considered for the calculations. Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
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End point timeframe:

pre-infusion and 1, 24, 168, 240 and 336 hours after completion of the sabatolimab infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. The duration of one cycle was 28 days.

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14 ^[71]	9 ^[72]	16 ^[73]	5 ^[74]
Units: hours				
median (full range (min-max))				
Cycle 1	1.53 (1.5 to 2.08)	1.5 (0.667 to 24.4)	1.57 (1.42 to 1.88)	1.53 (1.5 to 22.6)
Cycle 3	1.54 (1.5 to 1.67)	1.58 (0.583 to 24.5)	1.53 (0.483 to 1.93)	1.7 (1.7 to 1.7)

Notes:

[71] - n=14 (Cycle 1), 8 (Cycle 3)

[72] - n=9 (Cycle 1), 5 (Cycle 3)

[73] - n=16 (Cycle 1), 10 (Cycle 3)

[74] - n=5 (Cycle 1), 1 (Cycle 3)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[75]	4 ^[76]	6 ^[77]	2 ^[78]
Units: hours				
median (full range (min-max))				

Cycle 1	1.57 (1.53 to 1.6)	1.57 (1.55 to 1.67)	1.56 (1.5 to 1.62)	1.53 (1.52 to 1.55)
Cycle 3	999 (999 to 999)	999 (999 to 999)	1.55 (1.48 to 1.58)	1.62 (1.62 to 1.62)

Notes:

[75] - n=2 (Cycle 1), 0 (Cycle 3)

[76] - n=4 (Cycle 1), 0 (Cycle 3)

[77] - n=6 (Cycle 1), 3 (Cycle 3)

[78] - n=2 (Cycle 1), 1 (Cycle 3)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[79]	9 ^[80]	6 ^[81]	6 ^[82]
Units: hours				
median (full range (min-max))				
Cycle 1	1.58 (1.5 to 2)	1.5 (1.42 to 2.17)	1.53 (1.48 to 23.2)	1.55 (1.52 to 1.6)
Cycle 3	1.21 (0.833 to 1.58)	1.63 (1.58 to 1.67)	1.5 (1.5 to 1.5)	1.57 (1.55 to 1.58)

Notes:

[79] - n=8 (Cycle 1), 2 (Cycle 3)

[80] - n=9 (Cycle 1), 2 (Cycle 3)

[81] - n=6 (Cycle 1), 1 (Cycle 3)

[82] - n=6 (Cycle 1), 2 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[83]	13 ^[84]	6 ^[85]	4 ^[86]
Units: hours				
median (full range (min-max))				
Cycle 1	4 (4 to 4)	3.08 (2.72 to 4.08)	3.13 (1.53 to 4.08)	3.09 (1.17 to 3.33)
Cycle 3	3.25 (3.25 to 3.25)	3.31 (3 to 164)	3 (1.62 to 3.08)	999 (999 to 999)

Notes:

[83] - n=6 (Cycle 1), 1 (Cycle 3)

[84] - n=13 (Cycle 1), 8 (Cycle 3)

[85] - n=6 (Cycle 1), 3 (Cycle 3)

[86] - n=4 (Cycle 1), 0 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[87]	6 ^[88]	6 ^[89]	3 ^[90]
Units: hours				

median (full range (min-max))				
Cycle 1	3.08 (1.6 to 3.47)	3.48 (3.08 to 162)	3.32 (3.08 to 3.55)	3 (1.68 to 3.38)
Cycle 3	3.2 (3.03 to 3.3)	3.04 (3 to 3.08)	3.38 (3 to 19.7)	3 (3 to 3)

Notes:

[87] - n=4 (Cycle 1), 3 (Cycle 3)

[88] - n=6 (Cycle 1), 2 (Cycle 3)

[89] - n=6 (Cycle 1), 3 (Cycle 3)

[90] - n=3 (Cycle 1), 1 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12 ^[91]	5 ^[92]	6 ^[93]	6 ^[94]
Units: hours				
median (full range (min-max))				
Cycle 1	3.17 (2.52 to 4.12)	3.25 (1.55 to 359)	3.21 (3.07 to 21.9)	3.08 (3 to 4)
Cycle 3	3.13 (2.9 to 24)	3.04 (0 to 3.57)	3.08 (3.08 to 3.23)	3 (3 to 3.07)

Notes:

[91] - n=12 (Cycle 1), 8 (Cycle 3)

[92] - n=5 (Cycle 1), 4 (Cycle 3)

[93] - n=6 (Cycle 1), 5 (Cycle 3)

[94] - n=6 (Cycle 1), 4 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[95]	14 ^[96]	17 ^[97]	15 ^[98]
Units: hours				
median (full range (min-max))				
Cycle 1	3.23 (3.05 to 26.3)	1.5 (1.5 to 24.5)	1.58 (1.5 to 140)	1.67 (1.33 to 24.3)
Cycle 3	3.5 (3.5 to 3.5)	1.58 (1.5 to 1.65)	1.58 (1.5 to 1.7)	1.58 (1.57 to 23.8)

Notes:

[95] - n=4 (Cycle 1), 1 (Cycle 3)

[96] - n=14 (Cycle 1), 6 (Cycle 3)

[97] - n=17 (Cycle 1), 5 (Cycle 3)

[98] - n=15 (Cycle 1), 4 (Cycle 3)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15 ^[99]	16 ^[100]		
Units: hours				

median (full range (min-max))				
Cycle 1	3.37 (3 to 164)	3.15 (3 to 26)		
Cycle 3	3.08 (1.43 to 25)	3.24 (3.08 to 3.4)		

Notes:

[99] - n=15 (Cycle 1), 8 (Cycle 3)

[100] - n=16 (Cycle 1), 6 (Cycle 3)

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of sabatolimab

End point title	Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of sabatolimab
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End point description:

PK parameters were calculated based on sabatolimab serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUClast calculation.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
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End point timeframe:

pre-infusion and 1, 24, 168, 240 and 336 hours after completion of the sabatolimab infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. The duration of one cycle was 28 days.

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14 ^[101]	9 ^[102]	16 ^[103]	5 ^[104]
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	128 (± 33.2)	555 (± 191)	1670 (± 438)	2780 (± 862)
Cycle 3	172 (± 157)	1350 (± 576)	3270 (± 900)	4980 (± 999)

Notes:

[101] - n=14 (Cycle 1), 7 (Cycle 3)

[102] - n=9 (Cycle 1), 5 (Cycle 3)

[103] - n=16 (Cycle 1), 10 (Cycle 3)

[104] - n=5 (Cycle 1), 1 (Cycle 3)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[105]	4 ^[106]	6 ^[107]	2 ^[108]
Units: day*µg/mL				
arithmetic mean (standard deviation)				

Cycle 1	231 (± 4.77)	463 (± 47.9)	2070 (± 570)	3220 (± 107)
Cycle 3	999 (± 999)	999 (± 999)	2300 (± 407)	999 (± 999)

Notes:

[105] - n=2 (Cycle 1), 0 (Cycle 3)

[106] - n=4 (Cycle 1), 0 (Cycle 3)

[107] - n=6 (Cycle 1), 2 (Cycle 3)

[108] - n=2 (Cycle 1), 0 (Cycle 3)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7 ^[109]	8 ^[110]	6 ^[111]	6 ^[112]
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	851 (± 425)	2290 (± 793)	2800 (± 921)	4480 (± 1610)
Cycle 3	1100 (± 559)	3590 (± 1120)	2800 (± 999)	9080 (± 648)

Notes:

[109] - n=7 (Cycle 1), 2 (Cycle 3)

[110] - n=8 (Cycle 1), 2 (Cycle 3)

[111] - n=6 (Cycle 1), 1 (Cycle 3)

[112] - n=6 (Cycle 1), 2 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[113]	12 ^[114]	6 ^[115]	4 ^[116]
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	86.5 (± 999)	126 (± 34.7)	502 (± 146)	393 (± 197)
Cycle 3	321 (± 999)	357 (± 356)	824 (± 149)	999 (± 999)

Notes:

[113] - n=1 (Cycle 1), 1 (Cycle 3)

[114] - n=12 (Cycle 1), 8 (Cycle 3)

[115] - n=6 (Cycle 1), 3 (Cycle 3)

[116] - n=4 (Cycle 1), 0 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[117]	5 ^[118]	6 ^[119]	3 ^[120]
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	1550 (± 115)	1450 (± 546)	149 (± 63.1)	109 (± 57.5)
Cycle 3	3110 (± 721)	4040 (± 894)	165 (± 57.3)	124 (± 999)

Notes:

[117] - n=4 (Cycle 1), 3 (Cycle 3)

[118] - n=5 (Cycle 1), 2 (Cycle 3)

[119] - n=6 (Cycle 1), 3 (Cycle 3)

[120] - n=3 (Cycle 1), 1 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12 ^[121]	5 ^[122]	6 ^[123]	6 ^[124]
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	673 (± 245)	606 (± 302)	702 (± 329)	1870 (± 570)
Cycle 3	710 (± 337)	1310 (± 603)	989 (± 425)	2690 (± 1060)

Notes:

[121] - n=12 (Cycle 1), 8 (Cycle 3)

[122] - n=5 (Cycle 1), 4 (Cycle 3)

[123] - n=6 (Cycle 1), 5 (Cycle 3)

[124] - n=6 (Cycle 1), 4 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[125]	12 ^[126]	17 ^[127]	15 ^[128]
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	3450 (± 2020)	216 (± 85.3)	805 (± 278)	3710 (± 1280)
Cycle 3	3530 (± 999)	223 (± 75.5)	892 (± 499)	3730 (± 1640)

Notes:

[125] - n=4 (Cycle 1), 1 (Cycle 3)

[126] - n=12 (Cycle 1), 6 (Cycle 3)

[127] - n=17 (Cycle 1), 5 (Cycle 3)

[128] - n=15 (Cycle 1), 4 (Cycle 3)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15 ^[129]	16 ^[130]		
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	1820 (± 735)	2430 (± 988)		
Cycle 3	3060 (± 1230)	4390 (± 1610)		

Notes:

[129] - n=15 (Cycle 1), 8 (Cycle 3)

[130] - n=16 (Cycle 1), 6 (Cycle 3)

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal elimination half-life (T1/2) of sabatolimab

End point title	Terminal elimination half-life (T1/2) of sabatolimab
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End point description:

PK parameters were calculated based on sabatolimab serum concentrations by using non-compartmental methods. Elimination half-life (T1/2) values were calculated as 0.693/terminal elimination rate constant. Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
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End point timeframe:

pre-infusion and 1, 24, 168, 240 and 336 hours after completion of the sabatolimab infusion on Cycle 3 Day 1. The duration of the infusion was 30 minutes. The duration of one cycle was 28 days.

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	9	1
Units: days				
arithmetic mean (standard deviation)	8.6 (± 4.9)	16.5 (± 6.61)	13.5 (± 5.1)	33.8 (± 999)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[131]	0 ^[132]	2	0 ^[133]
Units: days				
arithmetic mean (standard deviation)	()	()	12.1 (± 2.35)	()

Notes:

[131] - No values available (n=0)

[132] - No values available (n=0)

[133] - No values available (n=0)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	1	2
Units: days				
arithmetic mean (standard deviation)	23.3 (± 11.1)	13.7 (± 1.8)	6.38 (± 999)	14.3 (± 13)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	7	2	0 ^[134]
Units: days				
arithmetic mean (standard deviation)	17.5 (± 999)	13.7 (± 11.6)	16.5 (± 7.69)	()

Notes:

[134] - No values available (n=0)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	3	1
Units: days				
arithmetic mean (standard deviation)	17.6 (± 0.142)	14.9 (± 6.72)	6.46 (± 1.55)	6.8 (± 999)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	4	5	4
Units: days				
arithmetic mean (standard deviation)	11.2 (± 5.27)	16.4 (± 7.48)	11.6 (± 3.66)	13.9 (± 1.48)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	5	5	3
Units: days				
arithmetic mean (standard deviation)	11.5 (± 999)	5.85 (± 1.77)	12 (± 4.33)	12.9 (± 5.62)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: days				
arithmetic mean (standard deviation)	19.1 (± 8.69)	21.7 (± 2.14)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum observed serum concentration (Cmax) of spartalizumab

End point title	Maximum observed serum concentration (Cmax) of spartalizumab ^[135]
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End point description:

PK parameters were calculated based on spartalizumab serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed serum concentration following a dose.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
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End point timeframe:

pre-infusion and 1, 24, 168, 240 and 336 hours after completion of the spartalizumab infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. The duration of one cycle was 28 days.

Notes:

[135] - 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 applies to MBG453+PDR001 arms

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[136]	13 ^[137]	6 ^[138]	4 ^[139]
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	21.3 (± 14.9)	24.8 (± 7.8)	20.1 (± 5.36)	66.2 (± 12.2)
Cycle 3	38.4 (± 12)	40.6 (± 7.09)	34.5 (± 6.59)	50 (± 999)

Notes:

[136] - n=6 (Cycle 1), 6 (Cycle 3)

[137] - n=13 (Cycle 1), 8 (Cycle 3)

[138] - n=6 (Cycle 1), 3 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[140]	6 ^[141]	6 ^[142]	3 ^[143]
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	18.6 (± 4.5)	71.9 (± 23.8)	28.8 (± 18.6)	78.1 (± 35.2)
Cycle 3	40.2 (± 6.12)	125 (± 5.66)	27 (± 3.77)	122 (± 7.07)

Notes:

[140] - n=5 (Cycle 1), 3 (Cycle 3)

[141] - n=6 (Cycle 1), 2 (Cycle 3)

[142] - n=6 (Cycle 1), 4 (Cycle 3)

[143] - n=3 (Cycle 1), 2 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12 ^[144]	5 ^[145]	7 ^[146]	6 ^[147]
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	24.3 (± 20.6)	65.1 (± 23.1)	121 (± 30)	113 (± 27)
Cycle 3	24 (± 12.5)	97 (± 27.7)	152 (± 40.2)	134 (± 38.2)

Notes:

[144] - n=12 (Cycle 1), 8 (Cycle 3)

[145] - n=5 (Cycle 1), 4 (Cycle 3)

[146] - n=7 (Cycle 1), 5 (Cycle 3)

[147] - n=6 (Cycle 1), 4 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6 ^[148]	17 ^[149]	16 ^[150]	
Units: µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	112 (± 35.8)	98.1 (± 29.1)	126 (± 42.1)	
Cycle 3	80.5 (± 999)	143 (± 46.5)	174 (± 63.5)	

Notes:

[148] - n=6 (Cycle 1), 1 (Cycle 3)

[149] - n=17 (Cycle 1), 8 (Cycle 3)

[150] - n=16 (Cycle 1), 9 (Cycle 3)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to reach maximum serum concentration (Tmax) of spartalizumab

End point title	Time to reach maximum serum concentration (Tmax) of spartalizumab ^[151]
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End point description:

PK parameters were calculated based on spartalizumab serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) serum concentration following a dose. Actual recorded sampling times were considered for the calculations. Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
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End point timeframe:

pre-infusion and 1, 24, 168, 240 and 336 hours after completion of the spartalizumab infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. The duration of one cycle was 28 days.

Notes:

[151] - 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 applies to MBG453+PDR001 arms

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[152]	12 ^[153]	6 ^[154]	4 ^[155]
Units: hours				
median (full range (min-max))				
Cycle 1	1.67 (1.52 to 23.3)	1.58 (1.33 to 23.6)	1.83 (1.5 to 23)	1.63 (1.52 to 2.08)
Cycle 3	1.78 (1.53 to 21.2)	1.5 (1.5 to 335)	1.58 (1.5 to 21.2)	999 (999 to 999)

Notes:

[152] - n=6 (Cycle 1), 5 (Cycle 3)

[153] - n=12 (Cycle 1), 8 (Cycle 3)

[154] - n=6 (Cycle 1), 3 (Cycle 3)

[155] - n=4 (Cycle 1), 0 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[156]	5 ^[157]	6 ^[158]	3 ^[159]
Units: hours				
median (full range (min-max))				
Cycle 1	1.57 (1.5 to 23.3)	1.67 (1.57 to 1.92)	1.61 (1.52 to 1.75)	1.58 (1.5 to 23.2)
Cycle 3	1.58 (1.53 to 1.6)	13 (1.5 to 24.6)	1.72 (1.18 to 21.2)	1.5 (1.5 to 1.5)

Notes:

[156] - n=5 (Cycle 1), 3 (Cycle 3)

[157] - n=5 (Cycle 1), 2 (Cycle 3)

[158] - n=6 (Cycle 1), 3 (Cycle 3)

[159] - n=3 (Cycle 1), 1 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12 ^[160]	5 ^[161]	7 ^[162]	6 ^[163]
Units: hours				
median (full range (min-max))				
Cycle 1	1.63 (1.1 to 22.2)	1.53 (1.45 to 21.9)	1.65 (1.57 to 22.6)	1.5 (1.43 to 2)
Cycle 3	1.5 (1.42 to 1.8)	1.52 (1.5 to 1.58)	1.58 (1.57 to 1.58)	1.5 (1.5 to 1.57)

Notes:

[160] - n=12 (Cycle 1), 8 (Cycle 3)

[161] - n=5 (Cycle 1), 4 (Cycle 3)

[162] - n=7 (Cycle 1), 5 (Cycle 3)

[163] - n=6 (Cycle 1), 4 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5 ^[164]	15 ^[165]	16 ^[166]	
Units: hours				
median (full range (min-max))				
Cycle 1	1.58 (1.55 to 1.68)	1.58 (1.5 to 3)	1.58 (1.37 to 2)	
Cycle 3	165 (165 to 165)	1.58 (1.5 to 24.5)	1.56 (1.52 to 1.62)	

Notes:

[164] - n=5 (Cycle 1), 1 (Cycle 3)

[165] - n=15 (Cycle 1), 8 (Cycle 3)

[166] - n=16 (Cycle 1), 6 (Cycle 3)

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of spartalizumab

End point title	Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of spartalizumab ^[167]
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End point description:

PK parameters were calculated based on spartalizumab serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUClast calculation. Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not

applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
End point timeframe:	
pre-infusion and 1, 24, 168, 240 and 336 hours after completion of the spartalizumab infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. The duration of one cycle was 28 days.	

Notes:

[167] - 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 applies to MBG453+PDR001 arms

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[168]	12 ^[169]	6 ^[170]	4 ^[171]
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	197 (± 61.5)	166 (± 44.3)	160 (± 45.5)	470 (± 173)
Cycle 3	366 (± 147)	389 (± 123)	314 (± 43)	999 (± 999)

Notes:

[168] - n=4 (Cycle 1), 5 (Cycle 3)

[169] - n=12 (Cycle 1), 8 (Cycle 3)

[170] - n=6 (Cycle 1), 3 (Cycle 3)

[171] - n=4 (Cycle 1), 0 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[172]	5 ^[173]	6 ^[174]	3 ^[175]
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	152 (± 45.3)	502 (± 157)	279 (± 89.5)	888 (± 452)
Cycle 3	348 (± 74.2)	1280 (± 213)	355 (± 58.4)	1800 (± 999)

Notes:

[172] - n=5 (Cycle 1), 3 (Cycle 3)

[173] - n=5 (Cycle 1), 2 (Cycle 3)

[174] - n=6 (Cycle 1), 3 (Cycle 3)

[175] - n=3 (Cycle 1), 1 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12 ^[176]	5 ^[177]	7 ^[178]	6 ^[179]
Units: day*µg/mL				

arithmetic mean (standard deviation)				
Cycle 1	291 (± 313)	773 (± 289)	1300 (± 735)	1120 (± 366)
Cycle 3	266 (± 154)	1540 (± 558)	2080 (± 837)	1680 (± 610)

Notes:

[176] - n=12 (Cycle 1), 8 (Cycle 3)

[177] - n=5 (Cycle 1), 4 (Cycle 3)

[178] - n=7 (Cycle 1), 5 (Cycle 3)

[179] - n=6 (Cycle 1), 4 (Cycle 3)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5 ^[180]	15 ^[181]	16 ^[182]	
Units: day*µg/mL				
arithmetic mean (standard deviation)				
Cycle 1	1180 (± 501)	1070 (± 322)	1570 (± 747)	
Cycle 3	1620 (± 999)	1870 (± 775)	2890 (± 741)	

Notes:

[180] - n=5 (Cycle 1), 1 (Cycle 3)

[181] - n=15 (Cycle 1), 8 (Cycle 3)

[182] - n=16 (Cycle 1), 6 (Cycle 3)

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal elimination half-life (T1/2) of spartalizumab

End point title	Terminal elimination half-life (T1/2) of spartalizumab ^[183]
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End point description:

PK parameters were calculated based on spartalizumab serum concentrations by using non-compartmental methods. Elimination half-life (T1/2) values were calculated as 0.693/terminal elimination rate constant.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
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End point timeframe:

pre-infusion and 1, 24, 168, 240 and 336 hours after completion of the spartalizumab infusion on Cycle 3 Day 1. The duration of the infusion was 30 minutes. The duration of one cycle was 28 days.

Notes:

[183] - 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 applies to MBG453+PDR001 arms

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	2	0 ^[184]
Units: days				

arithmetic mean (standard deviation)	13.7 (± 6.46)	19.9 (± 13.9)	29.5 (± 19.4)	()
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Notes:

[184] - No values available (n=0)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	1
Units: days				
arithmetic mean (standard deviation)	13.2 (± 1.14)	17.4 (± 9.53)	30.6 (± 23.5)	32.1 (± 999)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	3	5	4
Units: days				
arithmetic mean (standard deviation)	15.7 (± 5.6)	23.6 (± 8.82)	24.3 (± 9.72)	22.9 (± 6.19)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	7	5	
Units: days				
arithmetic mean (standard deviation)	28.7 (± 999)	24.5 (± 11.8)	22.7 (± 3.15)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with anti-sabatolimab antibodies

End point title	Number of participants with anti-sabatolimab antibodies
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End point description:

Immunogenicity was evaluated in serum in a validated three-tiered assay approach. Samples were screened for potential anti-sabatolimab antibodies and positive screen results were confirmed using a confirmatory assay. For confirmed anti-drug antibodies (ADA) positive samples, titers were determined. Patient ADA status was defined as follows:

- ADA-negative at baseline: ADA-negative sample at baseline

- ADA-positive at baseline: ADA-positive sample at baseline
- ADA-negative post-baseline: patient with ADA-negative sample at baseline and at least 1 post baseline determinant sample, all of which are ADA-negative samples
- ADA-inconclusive post-baseline = patient who does not qualify as ADA-positive or ADA-negative
- Treatment-induced ADA-positive = ADA-negative sample at baseline and at least 1 treatment-induced ADA-positive sample
- Treatment-boosted ADA-positive = ADA-positive sample at baseline and at least 1 treatment-boosted ADA-positive sample

End point type	Secondary
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End point timeframe:

Baseline (before first dose) and post-baseline (assessed throughout the treatment up to 1.9 years for sabatolimab and 4.9 years for sabatolimab in combination with spartalizumab)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[185]	8 ^[186]	14 ^[187]	5 ^[188]
Units: participants				
ADA-negative at baseline	5	8	14	5
ADA-positive at baseline	3	0	0	0
ADA-negative post-baseline	3	1	0	0
ADA- inconclusive post-baseline	3	7	14	5
Treatment-induced ADA-positive	1	0	0	0
Treatment-boosted ADA-positive	1	0	0	0

Notes:

[185] - n=8 (baseline), 8 (post-baseline)

[186] - n=8 (baseline), 8 (post-baseline)

[187] - n=14 (baseline), 14 (post-baseline)

[188] - n=5 (baseline), 5 (post-baseline)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[189]	4 ^[190]	6 ^[191]	2 ^[192]
Units: participants				
ADA-negative at baseline	2	4	6	2
ADA-positive at baseline	0	0	0	0
ADA-negative post-baseline	0	0	0	0
ADA- inconclusive post-baseline	2	3	6	2
Treatment-induced ADA-positive	0	1	0	0
Treatment-boosted ADA-positive	0	0	0	0

Notes:

[189] - n=2 (baseline), 2 (post-baseline)

[190] - n=4 (baseline), 4 (post-baseline)

[191] - n=6 (baseline), 6 (post-baseline)

[192] - n=2 (baseline), 2 (post-baseline)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[193]	7 ^[194]	5 ^[195]	6 ^[196]
Units: participants				
ADA-negative at baseline	5	7	5	6
ADA-positive at baseline	0	0	0	0
ADA-negative post-baseline	2	1	0	0
ADA- inconclusive post-baseline	2	6	5	6
Treatment-induced ADA-positive	1	0	0	0
Treatment-boosted ADA-positive	0	0	0	0

Notes:

[193] - n=5 (baseline), 5 (post-baseline)

[194] - n=7 (baseline), 7 (post-baseline)

[195] - n=5 (baseline), 5 (post-baseline)

[196] - n=6 (baseline), 6 (post-baseline)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[197]	13 ^[198]	5 ^[199]	5 ^[200]
Units: participants				
ADA-negative at baseline	6	12	4	5
ADA-positive at baseline	0	0	1	0
ADA-negative post-baseline	5	5	0	2
ADA- inconclusive post-baseline	0	7	3	2
Treatment-induced ADA-positive	1	1	1	1
Treatment-boosted ADA-positive	0	0	0	0

Notes:

[197] - n=6 (baseline), 6 (post-baseline)

[198] - n=12 (baseline), 13 (post-baseline)

[199] - n=5 (baseline), 4 (post-baseline)

[200] - n=5 (baseline), 5 (post-baseline)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[201]	5 ^[202]	6 ^[203]	2 ^[204]
Units: participants				
ADA-negative at baseline	4	4	5	2
ADA-positive at baseline	0	1	0	0
ADA-negative post-baseline	0	0	3	1
ADA- inconclusive post-baseline	4	4	2	1
Treatment-induced ADA-positive	0	0	1	0
Treatment-boosted ADA-positive	0	0	0	0

Notes:

[201] - n=4 (baseline), 4 (post-baseline)

[202] - n=5 (baseline), 4 (post-baseline)

[203] - n=5 (baseline), 6 (post-baseline)

[204] - n=2 (baseline), 2 (post-baseline)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12 ^[205]	5 ^[206]	5 ^[207]	6 ^[208]
Units: participants				
ADA-negative at baseline	12	5	4	5
ADA-positive at baseline	0	0	0	1
ADA-negative post-baseline	10	0	1	0
ADA- inconclusive post-baseline	2	4	3	6
Treatment-induced ADA-positive	0	1	1	0
Treatment-boosted ADA-positive	0	0	0	0

Notes:

[205] - n=12 (baseline), 12 (post-baseline)

[206] - n=5 (baseline), 5 (post-baseline)

[207] - n=4 (baseline), 5 (post-baseline)

[208] - n=6 (baseline), 6 (post-baseline)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[209]	11 ^[210]	13 ^[211]	12 ^[212]
Units: participants				
ADA-negative at baseline	1	9	12	10
ADA-positive at baseline	0	2	0	1
ADA-negative post-baseline	0	8	5	2
ADA- inconclusive post-baseline	2	2	7	10
Treatment-induced ADA-positive	0	1	1	0
Treatment-boosted ADA-positive	0	0	0	0

Notes:

[209] - n=1 (baseline), 2 (post-baseline)

[210] - n=11 (baseline), 11 (post-baseline)

[211] - n=12 (baseline), 13 (post-baseline)

[212] - n=11 (baseline), 12 (post-baseline)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[213]	14 ^[214]		
Units: participants				
ADA-negative at baseline	11	13		

ADA-positive at baseline	1	1		
ADA-negative post-baseline	1	0		
ADA- inconclusive post-baseline	10	14		
Treatment-induced ADA-positive	1	0		
Treatment-boosted ADA-positive	1	0		

Notes:

[213] - n=12 (baseline), 13 (post-baseline)

[214] - n=14 (baseline), 14 (post-baseline)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with anti-spartalizumab antibodies

End point title	Number of participants with anti-spartalizumab antibodies ^[215]
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End point description:

Immunogenicity was evaluated in serum in a validated three-tiered assay approach. Samples were screened for potential anti-spartalizumab antibodies and positive screen results were confirmed using a confirmatory assay. For confirmed anti-drug antibodies (ADA) positive samples, titers were determined. Patient ADA status was defined as follows:

- ADA-negative at baseline: ADA-negative sample at baseline
- ADA-positive at baseline: ADA-positive sample at baseline
- ADA-negative post-baseline: patient with ADA-negative sample at baseline and at least 1 post baseline determinant sample, all of which are ADA-negative samples
- ADA-inconclusive post-baseline = patient who does not qualify as ADA-positive or ADA-negative
- Treatment-induced ADA-positive = ADA-negative sample at baseline and at least 1 treatment-induced ADA-positive sample
- Treatment-boosted ADA-positive = ADA-positive sample at baseline and at least 1 treatment-boosted ADA-positive sample

End point type	Secondary
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End point timeframe:

Baseline (before first dose) and post-baseline (assessed throughout the treatment up to 4.9 years).

Notes:

[215] - 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 applies to MBG453+PDR001 arms

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[216]	12 ^[217]	5 ^[218]	5 ^[219]
Units: participants				
ADA-negative at baseline	4	9	3	5
ADA-positive at baseline	0	3	1	0
ADA-negative post-baseline	2	7	2	4
ADA- inconclusive post-baseline	1	1	2	1
Treatment-induced ADA-positive	2	1	0	0
Treatment-boosted ADA-positive	0	1	1	0

Notes:

[216] - n=4 (baseline), 5 (post-baseline)

[217] - n=12 (baseline), 10 (post-baseline)

[218] - n=4 (baseline), 5 (post-baseline)

[219] - n=5 (baseline), 5 (post-baseline)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[220]	5 ^[221]	6 ^[222]	2 ^[223]
Units: participants				
ADA-negative at baseline	4	4	5	2
ADA-positive at baseline	0	1	1	0
ADA-negative post-baseline	3	1	3	1
ADA- inconclusive post-baseline	1	4	1	1
Treatment-induced ADA-positive	0	0	1	0
Treatment-boosted ADA-positive	0	0	0	0

Notes:

[220] - n=4 (baseline), 4 (post-baseline)

[221] - n=5 (baseline), 5 (post-baseline)

[222] - n=6 (baseline), 5 (post-baseline)

[223] - n=2 (baseline), 2 (post-baseline)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11 ^[224]	5 ^[225]	4 ^[226]	6 ^[227]
Units: participants				
ADA-negative at baseline	9	4	3	6
ADA-positive at baseline	1	0	0	0
ADA-negative post-baseline	7	3	2	4
ADA- inconclusive post-baseline	2	2	2	1
Treatment-induced ADA-positive	1	0	0	1
Treatment-boosted ADA-positive	1	0	0	0

Notes:

[224] - n=10 (baseline), 11 (post-baseline)

[225] - n=4 (baseline), 5 (post-baseline)

[226] - n=3 (baseline), 4 (post-baseline)

[227] - n=6 (baseline), 6 (post-baseline)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3 ^[228]	13 ^[229]	13 ^[230]	
Units: participants				
ADA-negative at baseline	3	12	13	
ADA-positive at baseline	0	0	0	

ADA-negative post-baseline	2	6	7	
ADA- inconclusive post-baseline	1	6	6	
Treatment-induced ADA-positive	0	1	0	
Treatment-boosted ADA-positive	0	0	0	

Notes:

[228] - n=3 (baseline), 3 (post-baseline)

[229] - n=12 (baseline), 13 (post-baseline)

[230] - n=13 (baseline), 13 (post-baseline)

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline expression of PD-L1

End point title	Baseline expression of PD-L1
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End point description:

The tumor expression of programmed cell death-ligand 1 (PD-L1) was measured by immunohistochemical methods. This record summarizes the baseline expression of PD-1 and the clinical benefit of study treatment. Clinical benefit (BOR: CR, PR, SD or NCRNPD) and No clinical benefit (BOR: PD) was based on local investigator assessment per RECIST v1.1.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
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End point timeframe:

Screening

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[231]	5 ^[232]	9 ^[233]	5 ^[234]
Units: PD-L1 positivity percentage				
median (full range (min-max))				
Clinical benefit	0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)	0.00 (0.0 to 5.0)	999 (999 to 999)
No clinical benefit	0.00 (0.0 to 45.0)	5.00 (0.0 to 80.0)	0.00 (0.0 to 90.0)	0.00 (0.0 to 0.0)

Notes:

[231] - n= 2 (benefit), 6 (no benefit)

[232] - n= 2 (benefit), 3 (no benefit)

[233] - n= 4 (benefit), 5 (no benefit)

[234] - n= 0 (benefit), 5 (no benefit)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[235]	4 ^[236]	5 ^[237]	2 ^[238]
Units: PD-L1 positivity percentage				

median (full range (min-max))				
Clinical benefit	999 (999 to 999)	0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)	999 (999 to 999)
No clinical benefit	0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)	2.50 (0.0 to 5.0)

Notes:

[235] - n= 0 (benefit), 2 (no benefit)

[236] - n= 1 (benefit), 3 (no benefit)

[237] - n= 1 (benefit), 4 (no benefit)

[238] - n= 0 (benefit), 2 (no benefit)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[239]	3 ^[240]	3 ^[241]	6 ^[242]
Units: PD-L1 positivity percentage				
median (full range (min-max))				
Clinical benefit	0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)	999 (999 to 999)	0.00 (0.0 to 0.0)
No clinical benefit	0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)	0.00 (0.0 to 90.0)	0.00 (0.0 to 20.0)

Notes:

[239] - n= 1 (benefit), 3 (no benefit)

[240] - n= 1 (benefit), 2 (no benefit)

[241] - n= 0 (benefit), 3 (no benefit)

[242] - n= 3 (benefit), 3 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[243]	9 ^[244]	4 ^[245]	4 ^[246]
Units: PD-L1 positivity percentage				
median (full range (min-max))				
Clinical benefit	0.00 (0.0 to 10.0)	1.25 (0.0 to 80.0)	0.00 (0.0 to 0.0)	999 (999 to 999)
No clinical benefit	5.00 (5.0 to 5.0)	0.50 (0.0 to 70.0)	0.00 (0.0 to 0.0)	0.00 (0.0 to 1.0)

Notes:

[243] - n= 4 (benefit), 1 (no benefit)

[244] - n= 6 (benefit), 3 (no benefit)

[245] - n= 1 (benefit), 3 (no benefit)

[246] - n= 0 (benefit), 4 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[247]	3 ^[248]	4 ^[249]	1 ^[250]

Units: PD-L1 positivity percentage				
median (full range (min-max))				
Clinical benefit	5.00 (5.0 to 5.0)	0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)	999 (999 to 999)
No clinical benefit	0.00 (0.0 to 0.0)	2.50 (0.0 to 5.0)	5.00 (0.0 to 10.0)	40.00 (40.0 to 40.0)

Notes:

[247] - n= 1 (benefit), 3 (no benefit)

[248] - n= 1 (benefit), 2 (no benefit)

[249] - n= 2 (benefit), 2 (no benefit)

[250] - n= 0 (benefit), 1 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11 ^[251]	3 ^[252]	4 ^[253]	6 ^[254]
Units: PD-L1 positivity percentage				
median (full range (min-max))				
Clinical benefit	10.00 (0.0 to 90.0)	0.00 (0.0 to 0.0)	0.00 (0.0 to 1.0)	0.00 (0.0 to 35.0)
No clinical benefit	0.00 (0.0 to 80.0)	0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)	0.00 (0.0 to 0.0)

Notes:

[251] - n= 4 (benefit), 7 (no benefit)

[252] - n= 2 (benefit), 1 (no benefit)

[253] - n= 3 (benefit), 1 (no benefit)

[254] - n= 3 (benefit), 3 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[255]	11 ^[256]	14 ^[257]	11 ^[258]
Units: PD-L1 positivity percentage				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	0.00 (0.0 to 0.5)	22.50 (5.0 to 40.0)	0.00 (0.0 to 1.0)
No clinical benefit	60.00 (5.0 to 70.0)	0.00 (0.0 to 5.0)	0.00 (0.0 to 1.0)	0.00 (0.0 to 10.0)

Notes:

[255] - n= 0 (benefit), 3 (no benefit)

[256] - n= 4 (benefit), 7 (no benefit)

[257] - n= 2 (benefit), 12 (no benefit)

[258] - n= 4 (benefit), 7 (no benefit)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10 ^[259]	14 ^[260]		

Units: PD-L1 positivity percentage				
median (full range (min-max))				
Clinical benefit	80.0 (0.0 to 100.0)	7.75 (0.5 to 15.0)		
No clinical benefit	50.0 (0.0 to 100.0)	1.00 (0.0 to 50.0)		

Notes:

[259] - n= 5 (benefit), 5 (no benefit)

[260] - n= 2 (benefit), 12 (no benefit)

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline expression of CD8+

End point title	Baseline expression of CD8+
End point description:	
The tumor expression of CD8+ was measured by immunohistochemical methods. This record summarizes the baseline expression of CD8+ and the clinical benefit of study treatment. Clinical benefit (BOR: CR, PR, SD or NCRNPD) and No clinical benefit (BOR: PD) was based on local investigator assessment per RECIST v1.1.	
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.	
End point type	Secondary
End point timeframe:	
Screening	

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[261]	8 ^[262]	12 ^[263]	5 ^[264]
Units: percent marker area expression of CD8+				
median (full range (min-max))				
Clinical benefit	0.35 (0.1 to 2.0)	0.35 (0.0 to 0.7)	0.73 (0.3 to 35.8)	999 (999 to 999)
No clinical benefit	2.17 (0.2 to 21.5)	0.90 (0.2 to 1.4)	0.13 (0.0 to 13.2)	0.65 (0.5 to 0.7)

Notes:

[261] - n= 3 (benefit), 5 (no benefit)

[262] - n= 2 (benefit), 6 (no benefit)

[263] - n= 6 (benefit), 6 (no benefit)

[264] - n= 0 (benefit), 5 (no benefit)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[265]	4 ^[266]	4 ^[267]	2 ^[268]

Units: percent marker area expression of CD8+				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	1.00 (1.0 to 1.0)	5.54 (5.54 to 5.54)	999 (999 to 999)
No clinical benefit	4.28 (2.1 to 6.5)	0.21 (0.0 to 4.3)	0.37 (0.2 to 3.0)	0.68 (0.0 to 1.3)

Notes:

[265] - n= 0 (benefit), 2 (no benefit)

[266] - n= 1 (benefit), 3 (no benefit))

[267] - n= 1 (benefit), 3 (no benefit)

[268] - n= 0 (benefit), 2 (no benefit)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[269]	3 ^[270]	3 ^[271]	5 ^[272]
Units: percent marker area expression of CD8+				
median (full range (min-max))				
Clinical benefit	0.04 (0.0 to 0.1)	0.01 (0.01 to 0.01)	999 (999 to 999)	0.26 (0.2 to 1.4)
No clinical benefit	0.29 (0.1 to 0.5)	0.22 (0.1 to 0.3)	0.55 (0.3 to 3.1)	0.11 (0.11 to 0.11)

Notes:

[269] - n= 2 (benefit), 2 (no benefit)

[270] - n= 1 (benefit), 2 (no benefit)

[271] - n= 0 (benefit), 3 (no benefit)

[272] - n= 3 (benefit), 2 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[273]	8 ^[274]	4 ^[275]	4 ^[276]
Units: percent marker area expression of CD8+				
median (full range (min-max))				
Clinical benefit	0.47 (0.2 to 3.6)	2.07 (0.2 to 22.4)	0.09 (0.09 to 0.09)	999 (999 to 999)
No clinical benefit	4.76 (4.76 to 4.76)	4.58 (3.6 to 6.2)	1.25 (0.0 to 2.9)	0.42 (0.0 to 7.7)

Notes:

[273] - n= 5 (benefit), 1 (no benefit)

[274] - n= 5 (benefit), 3 (no benefit)

[275] - n= 1 (benefit), 3 (no benefit)

[276] - n= 0 (benefit), 4 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg
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	Q2W	Q2W	Q4W	Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[277]	3 ^[278]	4 ^[279]	1 ^[280]
Units: percent marker area expression of CD8+				
median (full range (min-max))				
Clinical benefit	8.32 (8.32 to 8.32)	0.03 (0.03 to 0.03)	0.08 (0.0 to 0.1)	999 (999 to 999)
No clinical benefit	0.16 (0.1 to 0.3)	3.56 (2.9 to 4.3)	0.10 (0.1 to 0.1)	0.96 (0.96 to 0.96)

Notes:

[277] - n= 1 (benefit), 3 (no benefit)

[278] - n= 1 (benefit), 2 (no benefit)

[279] - n= 2 (benefit), 2 (no benefit)

[280] - n= 0 (benefit), 1 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10 ^[281]	2 ^[282]	3 ^[283]	6 ^[284]
Units: percent marker area expression of CD8+				
median (full range (min-max))				
Clinical benefit	0.60 (0.0 to 54.0)	3.81 (2.7 to 4.9)	3.87 (0.1 to 7.7)	0.55 (0.1 to 8.3)
No clinical benefit	0.59 (0.1 to 5.3)	999 (999 to 999)	0.18 (0.18 to 0.18)	0.12 (0.1 to 0.2)

Notes:

[281] - n= 3 (benefit), 7 (no benefit)

[282] - n= 2 (benefit), 0 (no benefit)

[283] - n= 2 (benefit), 1 (no benefit)

[284] - n= 3 (benefit), 3 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[285]	11 ^[286]	14 ^[287]	11 ^[288]
Units: percent marker area expression of CD8+				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	0.90 (0.3 to 1.3)	0.60 (0.6 to 0.6)	0.11 (0.0 to 0.6)
No clinical benefit	0.11 (0.1 to 0.2)	0.16 (0.1 to 7.5)	0.71 (0.1 to 4.2)	0.38 (0.0 to 1.0)

Notes:

[285] - n= 0 (benefit), 3 (no benefit)

[286] - n= 4 (benefit), 7 (no benefit)

[287] - n= 2 (benefit), 12 (no benefit)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10 ^[289]	10 ^[290]		
Units: percent marker area expression of CD8+				
median (full range (min-max))				
Clinical benefit	7.08 (0.4 to 10.7)	6.67 (6.67 to 6.67)		
No clinical benefit	3.36 (0.8 to 4.5)	3.47 (0.2 to 10.0)		

Notes:

[289] - n= 5 (benefit), 5 (no benefit)

[290] - n= 1 (benefit), 9 (no benefit)

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline expression of TIM-3

End point title	Baseline expression of TIM-3
End point description:	
The tumor expression of T-cell Immunoglobulin domain and Mucin domain-3 (TIM-3) was measured by immunohistochemical methods. This record summarizes the baseline expression of TIM-3 and the clinical benefit of study treatment. Clinical benefit (BOR: CR, PR, SD or NCRNPD) and No clinical benefit (BOR: PD) was based on local investigator assessment per RECIST v1.1. Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.	
End point type	Secondary
End point timeframe:	
Screening	

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[291]	4 ^[292]	9 ^[293]	4 ^[294]
Units: percent marker area expression of TIM-3				
median (full range (min-max))				
Clinical benefit	3.01 (0.0 to 6.0)	2.56 (2.56 to 2.6)	6.68 (0.6 to 51.3)	999 (999 to 999)
No clinical benefit	9.32 (0.1 to 49.2)	6.10 (4.0 to 30.3)	3.96 (1.2 to 28.9)	0.99 (0.5 to 2.5)

Notes:

[291] - n= 2 (benefit), 6 (no benefit)

[292] - n= 2 (benefit), 3 (no benefit)

[293] - n= 4 (benefit), 5 (no benefit)

[294] - n= 0 (benefit), 4 (no benefit)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[295]	3 ^[296]	5 ^[297]	2 ^[298]
Units: percent marker area expression of TIM-3				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	6.06 (6.06 to 6.06)	41.00 (41.0 to 41.0)	999 (999 to 999)
No clinical benefit	10.93 (7.2 to 14.7)	0.88 (0.4 to 1.3)	6.74 (1.3 to 10.9)	5.49 (1.6 to 9.4)

Notes:

[295] - n= 0 (benefit), 2 (no benefit)

[296] - n= 1 (benefit), 2 (no benefit)

[297] - n= 1 (benefit), 4 (no benefit)

[298] - n= 0 (benefit), 2 (no benefit)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[299]	3 ^[300]	3 ^[301]	6 ^[302]
Units: percent marker area expression of TIM-3				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	1.05 (1.05 to 1.05)	999 (999 to 999)	6.26 (1.7 to 14.2)
No clinical benefit	4.82 (0.7 to 8.9)	2.70 (0.0 to 5.4)	15.88 (1.4 to 20.7)	2.36 (0.3 to 4.0)

Notes:

[299] - n= 0 (benefit), 2 (no benefit)

[300] - n= 1 (benefit), 2 (no benefit)

[301] - n= 0 (benefit), 3 (no benefit)

[302] - n= 3 (benefit), 3 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[303]	8 ^[304]	4 ^[305]	4 ^[306]
Units: percent marker area expression of TIM-3				
median (full range (min-max))				

Clinical benefit	4.19 (0.3 to 6.5)	15.19 (3.4 to 64.0)	0.04 (0.04 to 0.04)	999 (999 to 999)
No clinical benefit	32.23 (32.23 to 32.23)	47.27 (11.6 to 67.6)	11.29 (0.5 to 30.1)	7.27 (0.8 to 20.8)

Notes:

[303] - n= 4 (benefit), 1 (no benefit)

[304] - n= 5 (benefit), 3 (no benefit)

[305] - n= 1 (benefit), 3 (no benefit)

[306] - n= 0 (benefit), 4 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[307]	3 ^[308]	4 ^[309]	1 ^[310]
Units: percent marker area expression of TIM-3				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	0.66 (0.66 to 0.66)	0.40 (0.2 to 0.6)	999 (999 to 999)
No clinical benefit	1.89 (0.3 to 11.3)	8.92 (8.1 to 9.7)	2.13 (0.2 to 4.1)	52.24 (52.24 to 52.24)

Notes:

[307] - n= 0 (benefit), 3 (no benefit)

[308] - n= 1 (benefit), 2 (no benefit)

[309] - n= 2 (benefit), 2 (no benefit)

[310] - n= 0 (benefit), 1 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10 ^[311]	3 ^[312]	4 ^[313]	6 ^[314]
Units: percent marker area expression of TIM-3				
median (full range (min-max))				
Clinical benefit	7.13 (1.3 to 8.1)	17.81 (8.9 to 26.8)	11.27 (0.9 to 12.4)	14.57 (0.7 to 20.3)
No clinical benefit	6.74 (3.5 to 17.2)	0.84 (0.84 to 0.84)	0.37 (0.37 to 0.37)	2.88 (1.1 to 7.1)

Notes:

[311] - n= 3 (benefit), 7 (no benefit)

[312] - n= 2 (benefit), 1 (no benefit)

[313] - n= 3 (benefit), 1 (no benefit)

[314] - n= 3 (benefit), 3 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[315]	11 ^[316]	14 ^[317]	11 ^[318]
Units: percent marker area expression of TIM-3				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	5.05 (1.5 to 8.6)	2.32 (0.9 to 3.7)	1.66 (0.1 to 8.4)
No clinical benefit	0.71 (0.6 to 0.8)	1.50 (1.2 to 12.3)	2.16 (0.1 to 22.9)	6.20 (0.7 to 19.7)

Notes:

[315] - n= 0 (benefit), 2 (no benefit)

[316] - n= 4 (benefit), 7 (no benefit)

[317] - n= 2 (benefit), 12 (no benefit)

[318] - n= 4 (benefit), 7 (no benefit)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9 ^[319]	10 ^[320]		
Units: percent marker area expression of TIM-3				
median (full range (min-max))				
Clinical benefit	7.78 (2.5 to 21.8)	28.92 (28.92 to 28.92)		
No clinical benefit	8.19 (6.7 to 28.0)	3.11 (0.6 to 17.7)		

Notes:

[319] - n= 4 (benefit), 5 (no benefit)

[320] - n= 1 (benefit), 9 (no benefit)

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline expression of LAG-3

End point title	Baseline expression of LAG-3
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End point description:

The tumor expression of lymphocyte-activation gene-3 (LAG-3) was measured by immunohistochemical methods. This record summarizes the baseline expression of LAG-3 and the clinical benefit of study treatment. Clinical benefit (BOR: CR, PR, SD or NCRNPD) and No clinical benefit (BOR: PD) was based on local investigator assessment per RECIST v1.1.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
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End point timeframe:

Screening

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[321]	4 ^[322]	8 ^[323]	4 ^[324]
Units: percent marker area expression of LAG-3				
median (full range (min-max))				
Clinical benefit	0.24 (0.0 to 0.5)	0.08 (0.08 to 0.8)	0.23 (0.0 to 26.2)	999 (999 to 999)
No clinical benefit	1.61 (0.1 to 21.0)	0.69 (0.4 to 4.8)	2.68 (0.0 to 29.5)	0.11 (0.0 to 0.3)

Notes:

[321] - n= 2 (benefit), 6 (no benefit)

[322] - n= 1 (benefit), 3 (no benefit)

[323] - n= 4 (benefit), 4 (no benefit)

[324] - n= 0 (benefit), 4 (no benefit)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[325]	3 ^[326]	4 ^[327]	2 ^[328]
Units: percent marker area expression of LAG-3				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	1.30 (1.3 to 1.3)	7.12 (7.12 to 7.12)	999 (999 to 999)
No clinical benefit	2.11 (1.0 to 3.2)	0.02 (0.01 to 0.02)	0.14 (0.0 to 1.5)	0.58 (0.0 to 1.2)

Notes:

[325] - n= 0 (benefit), 2 (no benefit)

[326] - n= 1 (benefit), 2 (no benefit)

[327] - n= 1 (benefit), 3 (no benefit)

[328] - n= 0 (benefit), 2 (no benefit)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[329]	2 ^[330]	3 ^[331]	6 ^[332]
Units: percent marker area expression of LAG-3				
median (full range (min-max))				
Clinical benefit	0.03 (0.03 to 0.03)	999 (999 to 999)	999 (999 to 999)	0.02 (0.0 to 0.3)
No clinical benefit	0.10 (0.0 to 0.2)	0.05 (0.0 to 0.1)	0.18 (0.18 to 2.4)	0.06 (0.0 to 0.1)

Notes:

[329] - n= 1 (benefit), 2 (no benefit)

[330] - n= 0 (benefit), 2 (no benefit)

[331] - n= 0 (benefit), 3 (no benefit)

[332] - n= 3 (benefit), 3 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[333]	8 ^[334]	4 ^[335]	4 ^[336]
Units: percent marker area expression of LAG-3				
median (full range (min-max))				
Clinical benefit	0.31 (0.3 to 0.4)	2.44 (0.0 to 32.1)	0.00 (0.0 to 0.0)	999 (999 to 999)
No clinical benefit	7.63 (7.63 to 7.63)	1.49 (0.9 to 6.2)	0.78 (0.0 to 1.8)	0.30 (0.1 to 2.4)

Notes:

[333] - n= 4 (benefit), 1 (no benefit)

[334] - n= 5 (benefit), 3 (no benefit)

[335] - n= 1 (benefit), 3 (no benefit)

[336] - n= 0 (benefit), 4 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[337]	3 ^[338]	4 ^[339]	1 ^[340]
Units: percent marker area expression of LAG-3				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	0.01 (0.01 to 0.01)	0.01 (0.0 to 0.01)	999 (999 to 999)
No clinical benefit	0.05 (0.0 to 0.2)	1.33 (1.1 to 1.6)	0.07 (0.0 to 0.1)	0.08 (0.08 to 0.08)

Notes:

[337] - n= 0 (benefit), 3 (no benefit)

[338] - n= 1 (benefit), 2 (no benefit)

[339] - n= 2 (benefit), 2 (no benefit)

[340] - n= 0 (benefit), 1 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10 ^[341]	2 ^[342]	4 ^[343]	6 ^[344]
Units: percent marker area expression of LAG-3				
median (full range (min-max))				
Clinical benefit	0.20 (0.1 to 0.2)	2.08 (2.08 to 2.08)	0.31 (0.0 to 1.7)	0.83 (0.0 to 4.2)

No clinical benefit	0.33 (0.0 to 4.7)	0.00 (0.0 to 0.0)	0.05 (0.05 to 0.05)	0.06 (0.0 to 0.1)
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Notes:

[341] - n= 3 (benefit), 7 (no benefit)

[342] - n= 1 (benefit), 1 (no benefit)

[343] - n= 3 (benefit), 1 (no benefit)

[344] - n= 3 (benefit), 3 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[345]	11 ^[346]	12 ^[347]	11 ^[348]
Units: percent marker area expression of LAG-3				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	0.35 (0.1 to 1.1)	0.16 (0.1 to 0.3)	0.04 (0.0 to 0.5)
No clinical benefit	0.03 (0.0 to 0.1)	0.04 (0.0 to 4.0)	0.43 (0.0 to 1.3)	0.06 (0.0 to 0.8)

Notes:

[345] - n= 0 (benefit), 3 (no benefit)

[346] - n= 4 (benefit), 7 (no benefit)

[347] - n= 2 (benefit), 10 (no benefit)

[348] - n= 4 (benefit), 7 (no benefit)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10 ^[349]	12 ^[350]		
Units: percent marker area expression of LAG-3				
median (full range (min-max))				
Clinical benefit	3.08 (0.2 to 19.0)	3.39 (3.39 to 3.39)		
No clinical benefit	1.98 (0.4 to 2.5)	0.57 (0.0 to 10.0)		

Notes:

[349] - n= 5 (benefit), 5 (no benefit)

[350] - n= 1 (benefit), 11 (no benefit)

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline expression of CD163

End point title	Baseline expression of CD163
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End point description:

The tumor expression of CD163 was measured by immunohistochemical methods. This record summarizes the baseline expression of CD163 and the clinical benefit of study treatment. Clinical benefit (BOR: CR, PR, SD or NCRNPD) and No clinical benefit (BOR: PD) was based on local investigator assessment per RECIST v1.1.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not

applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary
End point timeframe:	
Screening	

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[351]	8 ^[352]	13 ^[353]	5 ^[354]
Units: percent marker area expression of CD163				
median (full range (min-max))				
Clinical benefit	3.12 (1.0 to 20.5)	0.26 (0.2 to 0.3)	6.05 (0.5 to 40.2)	999 (999 to 999)
No clinical benefit	11.53 (4.3 to 36.6)	9.48 (3.4 to 14.8)	5.22 (3.2 to 31.3)	3.92 (0.8 to 4.9)

Notes:

[351] - n= 3 (benefit), 5 (no benefit)

[352] - n= 2 (benefit), 6 (no benefit)

[353] - n= 6 (benefit), 7 (no benefit)

[354] - n= 0 (benefit), 5 (no benefit)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[355]	3 ^[356]	4 ^[357]	2 ^[358]
Units: percent marker area expression of CD163				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	14.56 (14.56 to 14.56)	15.47 (15.47 to 15.47)	999 (999 to 999)
No clinical benefit	7.60 (6.0 to 9.2)	0.98 (0.9 to 1.0)	14.30 (7.5 to 15.1)	3.66 (2.2 to 5.1)

Notes:

[355] - n= 0 (benefit), 2 (no benefit)

[356] - n= 1 (benefit), 2 (no benefit)

[357] - n= 1 (benefit), 3 (no benefit)

[358] - n= 0 (benefit), 2 (no benefit)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[359]	3 ^[360]	3 ^[361]	6 ^[362]
Units: percent marker area expression of CD163				
median (full range (min-max))				

Clinical benefit	0.42 (0.3 to 0.6)	3.79 (3.79 to 3.79)	999 (999 to 999)	5.53 (5.4 to 14.0)
No clinical benefit	6.95 (1.6 to 12.3)	7.36 (1.7 to 13.0)	19.69 (10.8 to 20.5)	5.78 (1.9 to 7.7)

Notes:

[359] - n= 2 (benefit), 2 (no benefit)

[360] - n= 1 (benefit), 2 (no benefit)

[361] - n= 0 (benefit), 3 (no benefit)

[362] - n= 3 (benefit), 3 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[363]	8 ^[364]	4 ^[365]	4 ^[366]
Units: percent marker area expression of CD163				
median (full range (min-max))				
Clinical benefit	6.76 (1.8 to 10.2)	21.36 (3.1 to 58.7)	0.41 (0.41 to 0.41)	999 (999 to 999)
No clinical benefit	16.17 (16.17 to 16.17)	26.28 (24.3 to 70.4)	6.23 (3.3 to 28.2)	10.36 (4.6 to 289)

Notes:

[363] - n= 5 (benefit), 1 (no benefit)

[364] - n= 5 (benefit), 3 (no benefit)

[365] - n= 1 (benefit), 3 (no benefit)

[366] - n= 0 (benefit), 4 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[367]	3 ^[368]	4 ^[369]	1 ^[370]
Units: percent marker area expression of CD163				
median (full range (min-max))				
Clinical benefit	12.93 (12.93 to 12.93)	1.66 (1.66 to 1.66)	3.44 (2.7 to 4.2)	999 (999 to 999)
No clinical benefit	5.08 (1.4 to 33.6)	11.11 (4.7 to 17.5)	1.14 (0.6 to 1.7)	28.64 (28.64 to 28.64)

Notes:

[367] - n= 1 (benefit), 3 (no benefit)

[368] - n= 1 (benefit), 2 (no benefit)

[369] - n= 2 (benefit), 2 (no benefit)

[370] - n= 0 (benefit), 1 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10 ^[371]	2 ^[372]	3 ^[373]	6 ^[374]
Units: percent marker area expression of CD163				
median (full range (min-max))				
Clinical benefit	7.09 (4.2 to 8.9)	26.40 (26.40 to 26.40)	12.40 (4.2 to 20.6)	5.46 (1.5 to 35.8)
No clinical benefit	10.62 (5.4 to 17.5)	3.67 (3.67 to 3.67)	1.41 (1.41 to 1.41)	3.47 (2.5 to 23.1)

Notes:

[371] - n= 3 (benefit), 7 (no benefit)

[372] - n= 1 (benefit), 1 (no benefit)

[373] - n= 2 (benefit), 1 (no benefit)

[374] - n= 3 (benefit), 3 (no benefit)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[375]	10 ^[376]	12 ^[377]	11 ^[378]
Units: percent marker area expression of CD163				
median (full range (min-max))				
Clinical benefit	999 (999 to 999)	5.66 (4.4 to 7.7)	7.41 (1.8 to 13.1)	5.41 (0.1 to 13.1)
No clinical benefit	5.80 (3.9 to 6.1)	5.78 (0.6 to 18.5)	4.92 (1.6 to 31.2)	3.56 (2.0 to 11.6)

Notes:

[375] - n= 0 (benefit), 3 (no benefit)

[376] - n= 4 (benefit), 6 (no benefit)

[377] - n= 2 (benefit), 10 (no benefit)

[378] - n= 4 (benefit), 7 (no benefit)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8 ^[379]	10 ^[380]		
Units: percent marker area expression of CD163				
median (full range (min-max))				
Clinical benefit	16.34 (14.3 to 26.2)	36.59 (36.59 to 36.59)		
No clinical benefit	17.46 (10.9 to 26.7)	11.88 (4.0 to 54.8)		

Notes:

[379] - n= 4 (benefit), 4 (no benefit)

[380] - n= 1 (benefit), 9 (no benefit)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage change from baseline of Tumor Infiltrating Lymphocytes (TILs) count

End point title	Percentage change from baseline of Tumor Infiltrating Lymphocytes (TILs) count
End point description: The count of TILs was performed by hematoxylin and eosin stain.	
End point type	Secondary
End point timeframe: Baseline (screening) and post-baseline (assessed throughout the treatment up to maximum 193 days)	

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	6	0 ^[381]
Units: percentage change from baseline				
median (full range (min-max))	41.67 (-50.0 to 133.3)	-100.00 (-100.0 to -100.0)	-25.00 (-100.0 to 900.0)	(to)

Notes:

[381] - No values available (n=0)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0 ^[382]	0 ^[383]	0 ^[384]
Units: percentage change from baseline				
median (full range (min-max))	-50.00 (-50.0 to -50.0)	(to)	(to)	(to)

Notes:

[382] - No values available (n=0)

[383] - No values available (n=0)

[384] - No values available (n=0)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[385]	0 ^[386]	0 ^[387]	2
Units: percentage change from baseline				
median (full range (min-max))	(to)	(to)	(to)	-70.00 (-100.0 to -40.0)

Notes:

[385] - No values available (n=0)

[386] - No values available (n=0)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	2	1
Units: percentage change from baseline				
median (full range (min-max))	-75.00 (-100.0 to -50.0)	-66.67 (-66.67 to -66.67)	-25.00 (-50.0 to 0.0)	-50.00 (-50.0 to -50.0)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	0 ^[388]	0 ^[389]	1
Units: percentage change from baseline				
median (full range (min-max))	-50.00 (-100.0 to 0.0)	(to)	(to)	-97.50 (-97.5 to -97.5)

Notes:

[388] - No values available (n=0)

[389] - No values available (n=0)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0 ^[390]	0 ^[391]	0 ^[392]
Units: percentage change from baseline				
median (full range (min-max))	-87.50 (-87.5 to -87.5)	(to)	(to)	(to)

Notes:

[390] - No values available (n=0)

[391] - No values available (n=0)

[392] - No values available (n=0)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[393]	3	2	0 ^[394]
Units: percentage change from baseline				

median (full range (min-max))	(to)	-66.67 (-100.0 to 100.0)	550.00 (200.0 to 900.0)	(to)
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Notes:

[393] - No values available (n=0)

[394] - No values available (n=0)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: percentage change from baseline				
median (full range (min-max))	-40.95 (-70.1 to -11.8)	-48.43 (-48.43 to -48.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

End point title	Phase II: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period ^[395]
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End point description:

Number of participants with AEs and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs.

AE grades to characterize the severity of the AEs were based on the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. For CTCAE v4.03, Grade 1 = mild; Grade 2 = moderate; Grade 3 = severe; Grade 4 = life-threatening; Grade 5 = death related to AE.

The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.

End point type	Secondary
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End point timeframe:

From first dose of study medication up to 30 days after last dose, with a maximum duration of 3 years

Notes:

[395] - 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 applies to Phase II

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: participants				
AEs	16	15		
Treatment-related AEs	6	9		
AEs with grade ≥ 3	10	6		
Treatment-related AEs with grade ≥ 3	2	0		
SAEs	9	2		
Fatal SAEs	1	0		

AEs leading to discontinuation	2	1		
AEs leading to dose adjustment/interruption	4	0		
AEs requiring additional therapy	15	14		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Number of participants with dose reductions and dose interruptions of sabatolimab

End point title	Phase II: Number of participants with dose reductions and dose interruptions of sabatolimab ^[396]
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End point description:

Number of participants with at least one dose reduction of sabatolimab and number of participants with at least one dose interruption of sabatolimab.

End point type	Secondary
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End point timeframe:

From first dose of study medication up to last dose, with a maximum duration of 2.9 years

Notes:

[396] - 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 applies to Phase II

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: participants				
At least one dose reduction	0	0		
At least one dose interruption	3	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Dose intensity of sabatolimab

End point title	Phase II: Dose intensity of sabatolimab ^[397]
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End point description:

Dose intensity of sabatolimab was calculated as cumulative actual dose in milligrams divided by duration of exposure in days and then multiplied by 28 days.

End point type	Secondary
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End point timeframe:

From first dose of study medication up to last dose, with a maximum duration of 2.9 years

Notes:

[397] - 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 applies to Phase II

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: milligrams				
arithmetic mean (standard deviation)	772.94 (± 62.826)	800.00 (± 0.000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Dose intensity of spartalizumab

End point title	Phase II: Dose intensity of spartalizumab ^[398]
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End point description:

Dose intensity of spartalizumab was calculated as cumulative actual dose in milligrams divided by duration of exposure in days and then multiplied by 28 days.

End point type	Secondary
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End point timeframe:

From first dose of study medication up to last dose, with a maximum duration of 2.9 years

Notes:

[398] - 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 applies to Phase II

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: milligrams				
arithmetic mean (standard deviation)	386.47 (± 31.413)	400.00 (± 0.000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Number of participants with dose reductions and dose interruptions of spartalizumab

End point title	Phase II: Number of participants with dose reductions and dose
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End point description:

Number of participants with at least one dose reduction of spartalizumab and number of participants with at least one dose interruption of spartalizumab.

End point type Secondary

End point timeframe:

From first dose of study medication up to last dose, with a maximum duration of 2.9 years

Notes:

[399] - 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 applies to Phase II

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	16		
Units: participants				
At least one dose reduction	0	0		
At least one dose interruption	3	0		

Statistical analyses

No statistical analyses for this end point

Post-hoc: All-Collected Deaths

End point title All-Collected Deaths

End point description:

On-treatment and post-treatment safety follow-up deaths were collected from first dose of study medication to 30 days after last dose (sabatolimab single agent) and to 150 days after last dose (sabatolimab+spartalizumab). Survival follow-up deaths were collected from 31 days (sabatolimab) and 151 days (sabatolimab+spartalizumab) after last dose until end of study. All deaths refer to the sum of on-treatment and post-treatment safety follow-up deaths plus survival follow-up deaths.

End point type Post-hoc

End point timeframe:

On-treatment and post-treatment safety follow-up (FU) deaths: up to 2 years for sabatolimab and 5.3 years for sabatolimab + spartalizumab. Survival follow-up deaths: up to 2 years for sabatolimab and 5.3 years for sabatolimab + spartalizumab

End point values	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14 ^[400]	9 ^[401]	16 ^[402]	5 ^[403]
Units: participants				
On-treatment and post-treatment safety FU deaths	9	4	6	5

Survival FU deaths	3	4	7	0
All deaths	12	8	13	5

Notes:

[400] - n= 14 (on-treatment and safety FU), 5 (survival), 14 (all)

[401] - n= 9 (on-treatment and safety FU), 5 (survival), 9 (all)

[402] - n= 16 (on-treatment and safety FU), 10 (survival), 16 (all)

[403] - n= 5 (on-treatment and safety FU), 0 (survival), 5 (all)

End point values	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[404]	4 ^[405]	6 ^[406]	2 ^[407]
Units: participants				
On-treatment and post-treatment safety FU deaths	1	4	5	1
Survival FU deaths	1	0	1	1
All deaths	2	4	6	2

Notes:

[404] - n= 2 (on-treatment and safety FU), 1 (survival), 2 (all)

[405] - n= 4 (on-treatment and safety FU), 0 (survival), 4 (all)

[406] - n= 6 (on-treatment and safety FU), 1 (survival), 6 (all)

[407] - n= 2 (on-treatment and safety FU), 1 (survival), 2 (all)

End point values	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[408]	9 ^[409]	6 ^[410]	6 ^[411]
Units: participants				
On-treatment and post-treatment safety FU deaths	3	4	4	3
Survival FU deaths	3	3	1	3
All deaths	6	7	5	6

Notes:

[408] - n= 8 (on-treatment and safety FU), 5 (survival), 8 (all)

[409] - n= 9 (on-treatment and safety FU), 5 (survival), 9 (all)

[410] - n= 6 (on-treatment and safety FU), 2 (survival), 6 (all)

[411] - n= 6 (on-treatment and safety FU), 3 (survival), 6 (all)

End point values	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[412]	13 ^[413]	6 ^[414]	5 ^[415]
Units: participants				
On-treatment and post-treatment safety FU deaths	1	5	2	5
Survival FU deaths	2	4	3	0
All deaths	3	9	5	5

Notes:

[412] - n= 6 (on-treatment and safety FU), 5 (survival), 6 (all)

[413] - n= 13 (on-treatment and safety FU), 8 (survival), 13 (all)

[414] - n= 6 (on-treatment and safety FU), 4 (survival), 6 (all)

[415] - n= 5 (on-treatment and safety FU), 0 (survival), 5 (all)

End point values	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[416]	6 ^[417]	6 ^[418]	3 ^[419]
Units: participants				
On-treatment and post-treatment safety FU deaths	2	3	0	3
Survival FU deaths	2	2	2	0
All deaths	4	5	2	3

Notes:

[416] - n= 5 (on-treatment and safety FU), 3 (survival), 5 (all)

[417] - n= 6 (on-treatment and safety FU), 3 (survival), 6 (all)

[418] - n= 6 (on-treatment and safety FU), 6 (survival), 6 (all)

[419] - n= 3 (on-treatment and safety FU), 0 (survival), 3 (all)

End point values	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12 ^[420]	5 ^[421]	7 ^[422]	6 ^[423]
Units: participants				
On-treatment and post-treatment safety FU deaths	5	2	1	2
Survival FU deaths	6	2	3	2
All deaths	11	4	4	4

Notes:

[420] - n= 12 (on-treatment and safety FU), 7 (survival), 12 (all)

[421] - n= 5 (on-treatment and safety FU), 3 (survival), 5 (all)

[422] - n= 7 (on-treatment and safety FU), 6 (survival), 7 (all)

[423] - n= 6 (on-treatment and safety FU), 4 (survival), 6 (all)

End point values	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mg Q4W	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W	Dose Ranging Part: MBG453 1200mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[424]	14 ^[425]	17 ^[426]	15 ^[427]
Units: participants				
On-treatment and post-treatment safety FU deaths	4	8	9	6
Survival FU deaths	1	4	3	7
All deaths	5	12	12	13

Notes:

[424] - n= 6 (on-treatment and safety FU), 2 (survival), 6 (all)

[425] - n= 14 (on-treatment and safety FU), 6 (survival), 14 (all)

[426] - n= 17 (on-treatment and safety FU), 8 (survival), 17 (all)

[427] - n= 15 (on-treatment and safety FU), 9 (survival), 15 (all)

End point values	Phase II: MBG453 + PDR001 NSCLC	Phase II: MBG453 + PDR001 Melanoma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17 ^[428]	16 ^[429]		
Units: participants				
On-treatment and post-treatment safety FU deaths	9	6		
Survival FU deaths	8	7		
All deaths	17	13		

Notes:

[428] - n= 17 (on-treatment and safety FU), 8 (survival), 17 (all)

[429] - n= 16 (on-treatment and safety FU), 10 (survival), 16 (all)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were collected from first dose of study treatment to 30 days after last dose (sabatolimab single agent) and to 150 days after last dose (sabatolimab+spartalizumab), up to 2 years for sabatolimab and 5.3 years for sabatolimab+spartalizumab.

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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.1
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Reporting groups

Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q2W ROW
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 800mg Q2W ROW
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 240mg Q2W ROW
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 80mg Q2W ROW
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 80mg Q2W Japan
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q4W ROW
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q4W Japan
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Dose Ranging Part: MBG453 80mg Q4W
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Dose Ranging Part: MBG453 240mg Q4W
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 800mg Q4W ROW
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 240mg Q4W ROW
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 800mg Q2W Japan
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase I Dose Escalation: MBG453 240mg Q2W Japan
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Dose Ranging Part: MBG453 1200mg Q4W
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Reporting group description:

Safety data up to 30 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase II: MBG453 + PDR001 Melanoma
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase II: MBG453 + PDR001 NSCLC
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mgQ4W
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Reporting group description:

Safety data up to 150 days after last dose

Reporting group title	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W
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Reporting group description:

Safety data up to 150 days after last dose

Serious adverse events	Phase I Dose Escalation: MBG453 1200mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)	9 / 16 (56.25%)	1 / 9 (11.11%)
number of deaths (all causes)	5	6	4
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 peritoneum			
subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	0 / 9 (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
Pericardial neoplasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (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
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal oedema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (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
Vulvovaginal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	0 / 9 (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
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	2 / 16 (12.50%)	0 / 9 (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
Pleuritic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
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 arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, auditory			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Troponin increased subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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			
Lumbar vertebral fracture subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	0 / 9 (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
Spinal fracture subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (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
Left ventricular dysfunction subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 disorder			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 loss anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (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 obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (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
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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			
Eczema asteatotic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	0 / 9 (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

Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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			
Bacterial sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis viral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
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	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q4W ROW
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 14 (42.86%)	0 / 2 (0.00%)	4 / 6 (66.67%)
number of deaths (all causes)	9	1	4
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			

subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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
Metastases to peritoneum			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial neoplasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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	1 / 14 (7.14%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atelectasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 arrest			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, auditory			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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			

Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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			
Lumbar vertebral fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 loss anaemia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (7.14%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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
Colitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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
Haematochezia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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	2 / 14 (14.29%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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
Rectal haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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	3 / 14 (21.43%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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
Hepatic failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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			
Eczema asteatotic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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			
Bacterial sepsis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Clostridium difficile colitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis viral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 syncytial virus infection			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia bacteraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
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	Phase I Dose Escalation: MBG453 1200mg Q4W Japan	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	10 / 14 (71.43%)	8 / 17 (47.06%)
number of deaths (all causes)	3	8	9
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 peritoneum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Embolism			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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%)	1 / 14 (7.14%)	0 / 17 (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
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal oedema			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Dyspnoea			

subjects affected / exposed	0 / 6 (0.00%)	2 / 14 (14.29%)	0 / 17 (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
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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%)	2 / 14 (14.29%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Wheezing			

subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, auditory			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Lumbar vertebral fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (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

Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
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 loss anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	2 / 17 (11.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	2 / 17 (11.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Oesophageal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			

subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			

Eczema asteatotic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pathological fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Bacterial sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
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 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
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	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 9 (66.67%)	3 / 8 (37.50%)	0 / 2 (0.00%)
number of deaths (all causes)	4	3	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 peritoneum			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial neoplasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (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
Embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
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	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (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
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (11.11%)	1 / 8 (12.50%)	0 / 2 (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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	0 / 2 (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
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (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, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchial obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (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
Hallucination, auditory			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase			

increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
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			
Lumbar vertebral fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Left ventricular dysfunction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (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
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 loss anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (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
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (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
Impaired gastric emptying			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
Eczema asteatotic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (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 impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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			
Bacterial sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Escherichia urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis viral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia bacteraemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
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	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Dose Ranging Part: MBG453 1200mg Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	9 / 15 (60.00%)
number of deaths (all causes)	5	4	6
number of deaths resulting from	0	0	0

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 peritoneum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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			

Acute respiratory distress syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, auditory			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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			
Lumbar vertebral fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Wound complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Embolic stroke			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
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 loss anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 4 (0.00%)	3 / 15 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	2 / 15 (13.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Duodenal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	2 / 15 (13.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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			
Eczema asteatotic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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			
Bacterial sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Campylobacter gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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			
Decreased appetite			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
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	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 13 (53.85%)	2 / 6 (33.33%)	2 / 6 (33.33%)
number of deaths (all causes)	5	1	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 peritoneum			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial neoplasm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (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
Embolism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 6 (16.67%)	0 / 6 (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
Oedema peripheral			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (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
Reproductive system and breast disorders			
Pelvic pain			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (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
Scrotal oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (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
Bronchial obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Haemoptysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (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
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 arrest			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, auditory			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Troponin increased subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Lumbar vertebral fracture subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (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
Hemiparesis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 disorder			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (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
Somnolence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 loss anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Colitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Eczema asteatotic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Muscular weakness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Bacterial sepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis viral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (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 aspiration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (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
Serratia bacteraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	4 / 5 (80.00%)	0 / 6 (0.00%)
number of deaths (all causes)	5	2	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			

subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (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
Metastases to peritoneum			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial neoplasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (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
Pleuritic pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, auditory			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (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
Mental disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			

Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Lumbar vertebral fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 disorder			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 loss anaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (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
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Eczema asteatotic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (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
Pathological fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Bacterial sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (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
Respiratory syncytial virus infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W	Phase II: MBG453 + PDR001 Melanoma
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	1 / 3 (33.33%)	5 / 16 (31.25%)
number of deaths (all causes)	0	3	6
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 peritoneum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (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
Scrotal oedema			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, auditory			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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			
Lumbar vertebral fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (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
Blood loss anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (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
Oesophageal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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			

Eczema asteatotic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (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
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pathological fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 16 (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
Meningoencephalitis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 infection			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (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	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (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 aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (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
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
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	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	2 / 7 (28.57%)	4 / 6 (66.67%)
number of deaths (all causes)	2	1	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (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
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 peritoneum			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial neoplasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchial obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (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
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, auditory			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (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			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase			

increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Lumbar vertebral fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Left ventricular dysfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 loss anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
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			
Eczema asteatotic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Bacterial sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Escherichia urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia bacteraemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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	Phase II: MBG453 + PDR001 NSCLC	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mgQ4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 17 (52.94%)	5 / 6 (83.33%)	2 / 12 (16.67%)
number of deaths (all causes)	9	4	5

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial neoplasm			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena cava syndrome			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Acute respiratory distress syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	2 / 17 (11.76%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, auditory			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Lumbar vertebral fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Wound complication			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Embolic stroke			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Duodenal stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Eczema asteatotic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haematuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Campylobacter gastroenteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis viral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia bacteraemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Phase I Dose Escalation: MBG453 1200mg Q2W ROW	Phase I Dose Escalation: MBG453 800mg Q2W ROW	Phase I Dose Escalation: MBG453 240mg Q2W ROW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	14 / 16 (87.50%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Intracranial tumour haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour invasion			
subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Tumour associated fever			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Hypertension			
subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Thrombosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	1 / 5 (20.00%)	2 / 16 (12.50%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Chest discomfort			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	0
Catheter site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	0
Face oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 5 (40.00%)	6 / 16 (37.50%)	5 / 9 (55.56%)
occurrences (all)	2	7	4
Generalised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperpyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0

Pain			
subjects affected / exposed	1 / 5 (20.00%)	2 / 16 (12.50%)	0 / 9 (0.00%)
occurrences (all)	1	3	0
Swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vascular device occlusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Seasonal allergy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menopause			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Breast pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal odour			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	3 / 9 (33.33%)
occurrences (all)	0	3	3
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	1 / 5 (20.00%)	4 / 16 (25.00%)	4 / 9 (44.44%)
occurrences (all)	1	4	2
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			

subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 5 (20.00%)	2 / 16 (12.50%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	2	0
Delirium			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ammonia increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 5 (20.00%)	2 / 16 (12.50%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	2	0
Blood potassium decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Body temperature increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Coronavirus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis radiation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Radiation skin injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bradycardia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Aphasia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Cranial nerve disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Dizziness postural			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	0

Diabetic neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Facial paralysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dyskinesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	3 / 16 (18.75%)	0 / 9 (0.00%)
occurrences (all)	0	3	0
Hemiparesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Memory impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myasthenia gravis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Partial seizures			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Seizure			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	2 / 9 (22.22%)
occurrences (all)	0	2	2
Iron deficiency anaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Anaemia of malignant disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	3	0
Neutrophilia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Normocytic anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	2	0
Thrombocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cataract			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vitreous floaters			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	3 / 9 (33.33%)
occurrences (all)	1	0	1
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Anal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	2 / 16 (12.50%) 2	1 / 9 (11.11%) 1
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 16 (6.25%) 1	2 / 9 (22.22%) 2
Anal incontinence subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 16 (6.25%) 0	1 / 9 (11.11%) 0
Cheilitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	3 / 16 (18.75%) 3	0 / 9 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	4 / 16 (25.00%) 5	3 / 9 (33.33%) 1
Dry mouth subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	2 / 16 (12.50%) 2	3 / 9 (33.33%) 2
Gastritis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Flatulence subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Dysphagia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	5 / 16 (31.25%)	1 / 9 (11.11%)
occurrences (all)	0	7	3
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Rectal haemorrhage subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Rectal tenesmus subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	3 / 16 (18.75%) 6	2 / 9 (22.22%) 3
Hepatobiliary disorders			
Cholangitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hepatic failure subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 16 (6.25%) 1	0 / 9 (0.00%) 0
Hepatitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hypertransaminaemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	1 / 16 (6.25%) 1	0 / 9 (0.00%) 0
Jaundice subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	1 / 9 (11.11%) 0
Portal vein thrombosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Liver disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 5 (20.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Rash pruritic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Skin irritation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary retention			

subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 16 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Bone pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Bone cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Bursitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Fracture pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Muscular weakness			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Spinal pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Spinal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aerococcus urinae infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal viral infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hepatitis B reactivation subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Influenza subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Infected cyst subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Kidney infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Lip infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Lower respiratory tract infection bacterial subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Mucosal infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 16 (6.25%) 1	0 / 9 (0.00%) 0
Oral fungal infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tinea infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper aerodigestive tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 16 (6.25%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Vaginal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	2	0
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Glucose tolerance impaired subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	2 / 16 (12.50%) 2	1 / 9 (11.11%) 2
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hypermagnesaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hyperphosphataemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hypernatraemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0
Hypoglycaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0

Hypomagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 16 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypovitaminosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypouricaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I Dose Escalation: MBG453 80mg Q2W ROW	Phase I Dose Escalation: MBG453 80mg Q2W Japan	Phase I Dose Escalation: MBG453 1200mg Q4W ROW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 14 (92.86%)	2 / 2 (100.00%)	5 / 6 (83.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Intracranial tumour haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tumour invasion			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Tumour associated fever subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	1 / 2 (50.00%) 1	1 / 6 (16.67%) 1
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Haemorrhage subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Jugular vein thrombosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Thrombosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Subclavian vein thrombosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0

Peripheral embolism subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Venous thrombosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Chest discomfort subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Catheter site pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Axillary pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Early satiety subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Face oedema subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Facial pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Feeling cold			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 14 (28.57%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	4	0	1
Generalised oedema			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperpyrexia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nodule			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 14 (14.29%)	1 / 2 (50.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Peripheral swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular device occlusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 14 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Social circumstances			
Menopause			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal odour			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 14 (21.43%)	1 / 2 (50.00%)	1 / 6 (16.67%)
occurrences (all)	2	1	1

Epistaxis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pneumonitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Confusional state			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Delirium			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ammonia increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood albumin decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Weight increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis radiation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 14 (0.00%)	1 / 2 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cranial nerve disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diabetic neuropathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Myasthenia gravis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 14 (21.43%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anaemia of malignant disease			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lymphopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Leukopenia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Normocytic anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Thrombocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 14 (14.29%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Abdominal distension			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 14 (14.29%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Abdominal pain lower			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 14 (14.29%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Dry mouth			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 14 (14.29%)	1 / 2 (50.00%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Gastritis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	5 / 14 (35.71%)	0 / 2 (0.00%)	3 / 6 (50.00%)
occurrences (all)	4	0	3
Mouth ulceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Melaena			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 14 (14.29%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Jaundice subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Portal vein thrombosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Liver disorder subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Skin and subcutaneous tissue disorders			
Decubitus ulcer subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 2 (50.00%) 1	0 / 6 (0.00%) 0
Dermatitis subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Drug eruption subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	1 / 2 (50.00%) 0	0 / 6 (0.00%) 0
Ecchymosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0
Hidradenitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Psoriasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Rash pruritic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pollakiuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypopituitarism			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 14 (21.43%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Bone pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 14 (14.29%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Bursitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myositis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Polyarthrititis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal stenosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aerococcus urinae infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Cystitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatitis B reactivation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infected cyst			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper aerodigestive tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	6 / 14 (42.86%)	0 / 2 (0.00%)	3 / 6 (50.00%)
occurrences (all)	5	0	2

Dehydration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Hypernatraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Hypocalcaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	5 / 14 (35.71%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	7	0	0
Hyponatraemia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hypovitaminosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypouricaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	1 / 14 (7.14%)	0 / 2 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Phase I Dose Escalation: MBG453 1200mg Q4W Japan	Dose Ranging Part: MBG453 80mg Q4W	Dose Ranging Part: MBG453 240mg Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	13 / 14 (92.86%)	17 / 17 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	3 / 14 (21.43%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Intracranial tumour haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tumour invasion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	2 / 6 (33.33%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Hypotension			

subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 6 (16.67%)	2 / 14 (14.29%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Subclavian vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Early satiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 6 (33.33%)	4 / 14 (28.57%)	4 / 17 (23.53%)
occurrences (all)	1	4	3
Generalised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperpyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Injection site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Nodule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	3 / 6 (50.00%)	2 / 14 (14.29%)	1 / 17 (5.88%)
occurrences (all)	2	2	1
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Vascular device occlusion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Xerosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Contrast media allergy subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Social circumstances Menopause subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1	0 / 17 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1	0 / 17 (0.00%) 0
Menstruation irregular subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	1 / 17 (5.88%) 1
Pelvic discomfort subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Vaginal odour			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)	3 / 14 (21.43%)	1 / 17 (5.88%)
occurrences (all)	1	2	1
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	1
Respiratory tract congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	1 / 6 (16.67%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 6 (33.33%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	2	1	0
Ammonia increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	2 / 6 (33.33%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	2	1	1
Blood albumin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 6 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 6 (33.33%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Blood potassium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 6 (16.67%)	2 / 14 (14.29%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Liver function test increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis radiation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Procedural pain			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Radiation skin injury subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1	0 / 17 (0.00%) 0
Cardiac disorders Atrial thrombosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	1 / 17 (5.88%) 1
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1	0 / 17 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Nervous system disorders Balance disorder subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Ataxia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Aphasia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Cranial nerve disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Diabetic neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Myasthenia gravis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 6 (50.00%)	1 / 14 (7.14%)	4 / 17 (23.53%)
occurrences (all)	5	1	4

Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Anaemia of malignant disease subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	1 / 17 (5.88%) 1
Lymphopenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Leukopenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Neutrophilia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Normocytic anaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 14 (7.14%) 1	0 / 17 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Ear and labyrinth disorders Ear discomfort			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1

Vision blurred subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	1 / 17 (5.88%) 1
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 14 (14.29%) 3	3 / 17 (17.65%) 5
Abdominal distension subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 1	1 / 14 (7.14%) 1	0 / 17 (0.00%) 0
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	1 / 17 (5.88%) 1
Anal haemorrhage subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 14 (14.29%) 2	1 / 17 (5.88%) 1
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Anal incontinence subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	1 / 14 (7.14%) 1	3 / 17 (17.65%) 4
Cheilitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Dyspepsia			

subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	3 / 17 (17.65%)
occurrences (all)	0	1	3
Diarrhoea			
subjects affected / exposed	2 / 6 (33.33%)	2 / 14 (14.29%)	3 / 17 (17.65%)
occurrences (all)	1	2	3
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	4 / 14 (28.57%)	4 / 17 (23.53%)
occurrences (all)	0	4	4
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 6 (16.67%)	4 / 14 (28.57%)	3 / 17 (17.65%)
occurrences (all)	0	5	3
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	2 / 14 (14.29%)	4 / 17 (23.53%)
occurrences (all)	0	4	9
Hepatobiliary disorders			

Cholangitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypertransaminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Liver disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	2 / 6 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Ecchymosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hidradenitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Lichenoid keratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	2 / 14 (14.29%)	0 / 17 (0.00%)
occurrences (all)	0	2	0

Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	2 / 14 (14.29%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Chromaturia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypopituitarism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Flank pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	2
Myositis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Polyarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Spinal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aerococcus urinae infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dermatophytosis of nail			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hepatitis B reactivation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Kidney infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 14 (7.14%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Parotitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tinea infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Upper aerodigestive tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	2 / 14 (14.29%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Wound infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	3 / 6 (50.00%)	1 / 14 (7.14%)	4 / 17 (23.53%)
occurrences (all)	3	1	4
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Hyperglycaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Hyperphosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 14 (0.00%)	3 / 17 (17.65%)
occurrences (all)	1	0	4
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	1	0	2
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Hypovitaminosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypouricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 14 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2

Vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0
Iron deficiency subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 14 (0.00%) 0	0 / 17 (0.00%) 0

Non-serious adverse events	Phase I Dose Escalation: MBG453 800mg Q4W ROW	Phase I Dose Escalation: MBG453 240mg Q4W ROW	Phase I Dose Escalation: MBG453 1200mg Q2W Japan
Total subjects affected by non-serious adverse events subjects affected / exposed	9 / 9 (100.00%)	7 / 8 (87.50%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Cancer pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Intracranial tumour haemorrhage subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Tumour haemorrhage subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Tumour invasion subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Tumour associated fever subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 8 (12.50%) 1	1 / 2 (50.00%) 1
Vascular disorders Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0

Haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Chest discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Early satiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Facial pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Feeling cold			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 9 (22.22%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Generalised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperpyrexia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	2 / 2 (100.00%)
occurrences (all)	1	1	1
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	1 / 9 (11.11%)	3 / 8 (37.50%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
Vascular device occlusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menopause			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vaginal odour			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 9 (11.11%)	3 / 8 (37.50%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Nasal congestion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypoxia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	0	1	0
Ammonia increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Blood albumin decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 9 (22.22%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	2	1	1
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	2 / 2 (100.00%)
occurrences (all)	1	0	0
Blood potassium decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Body temperature increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis radiation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachycardia			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Cranial nerve disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diabetic neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Facial paralysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myasthenia gravis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 9 (33.33%)	3 / 8 (37.50%)	2 / 2 (100.00%)
occurrences (all)	5	4	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anaemia of malignant disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Neutrophilia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Normocytic anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutropenia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 9 (22.22%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Anal incontinence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 9 (0.00%)	4 / 8 (50.00%)	1 / 2 (50.00%)
occurrences (all)	0	4	1
Gastritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 9 (33.33%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	3	1	1
Mouth ulceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertransaminaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Jaundice			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Liver disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Decubitus ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Ecchymosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Hidradenitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	2	1	0

Psoriasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Strangury			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bone cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bursitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			

subjects affected / exposed	0 / 9 (0.00%)	2 / 8 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Myalgia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myositis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Polyarthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rhabdomyolysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sacral pain			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Spinal stenosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Infections and infestations			
Aerococcus urinae infection subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
COVID-19 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Cellulitis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Conjunctivitis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Cystitis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Dermatophytosis of nail subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Eye infection subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal viral infection subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0
Hepatitis B reactivation subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 8 (0.00%) 0	0 / 2 (0.00%) 0

Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Oral fungal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paronychia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper aerodigestive tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	1 / 2 (50.00%)
occurrences (all)	1	1	1
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Diabetes mellitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Hyperglycaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Hyperkalaemia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypernatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	0

Hypovitaminosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypouricaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I Dose Escalation: MBG453 800mg Q2W Japan	Phase I Dose Escalation: MBG453 240mg Q2W Japan	Dose Ranging Part: MBG453 1200mg Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	4 / 4 (100.00%)	14 / 15 (93.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Intracranial tumour haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tumour invasion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Tumour pain			

subjects affected / exposed occurrences (all)	4 / 6 (66.67%) 3	2 / 4 (50.00%) 1	0 / 15 (0.00%) 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Venous thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Early satiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	4 / 6 (66.67%)	0 / 4 (0.00%)	6 / 15 (40.00%)
occurrences (all)	4	0	7
Generalised oedema			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperpyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 6 (33.33%)	1 / 4 (25.00%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
Peripheral swelling			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	4 / 15 (26.67%)
occurrences (all)	20	1	4
Vascular device occlusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menopause			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Balanoposthitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vaginal odour			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
Epistaxis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 6 (33.33%)	1 / 4 (25.00%)	2 / 15 (13.33%)
occurrences (all)	2	1	2
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Respiratory tract congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 6 (33.33%)	1 / 4 (25.00%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Ammonia increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Blood albumin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 4 (25.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Liver function test increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Fall			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis radiation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bradycardia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cranial nerve disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2

Diabetic neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Myasthenia gravis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 4 (0.00%)	5 / 15 (33.33%)
occurrences (all)	3	0	8
Iron deficiency anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Anaemia of malignant disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Neutrophilia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	3
Normocytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cataract			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	4
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Abdominal pain upper			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Cheilitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	2 / 15 (13.33%)
occurrences (all)	1	0	2
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	1 / 4 (25.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	4
Large intestinal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	5 / 6 (83.33%)	0 / 4 (0.00%)	3 / 15 (20.00%)
occurrences (all)	3	0	4
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Oral discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Rectal tenesmus subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hepatobiliary disorders			
Cholangitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 4 (25.00%) 1	0 / 15 (0.00%) 0
Hepatic failure subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 4 (25.00%) 1	0 / 15 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hepatitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Jaundice subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Portal vein thrombosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Liver disorder			
subjects affected / exposed	3 / 6 (50.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	2 / 6 (33.33%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Psoriasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Vitiligo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urinary retention			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Bone pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Fracture pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Myositis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Spinal pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Spinal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Infections and infestations			
Aerococcus urinae infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal viral infection subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hepatitis B reactivation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	1 / 15 (6.67%) 1
Influenza subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Infected cyst subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Kidney infection subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Lip infection subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Lower respiratory tract infection bacterial subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Mucosal infection subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Oral fungal infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tinea infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Upper aerodigestive tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Viral rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	4 / 6 (66.67%)	2 / 4 (50.00%)	2 / 15 (13.33%)
occurrences (all)	1	2	2
Dehydration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Diabetes mellitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Glucose tolerance impaired subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	1 / 15 (6.67%) 1
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hypermagnesaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hyperphosphataemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hypernatraemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 0	0 / 4 (0.00%) 0	1 / 15 (6.67%) 1
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0
Hypoglycaemia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 0	0 / 4 (0.00%) 0	0 / 15 (0.00%) 0

Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Hyponatraemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hypovitaminosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypouricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ib Dose Escalation: MBG453 80mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 20mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 80mg Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 13 (92.31%)	6 / 6 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Intracranial tumour haemorrhage			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Tumour invasion subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Tumour associated fever subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Haemorrhage subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Jugular vein thrombosis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Thrombosis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Subclavian vein thrombosis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Axillary pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Face oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial pain			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	7 / 13 (53.85%)	1 / 6 (16.67%)	3 / 6 (50.00%)
occurrences (all)	7	1	4
Generalised oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hyperpyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 13 (15.38%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Peripheral swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 13 (15.38%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	3	0
Vascular device occlusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Social circumstances Menopause subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all) Breast pain subjects affected / exposed occurrences (all) Menstruation irregular subjects affected / exposed occurrences (all) Pelvic pain subjects affected / exposed occurrences (all) Pelvic discomfort subjects affected / exposed occurrences (all) Vaginal discharge subjects affected / exposed occurrences (all) Vaginal odour subjects affected / exposed occurrences (all) Vulvovaginal erythema subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Bronchial fistula subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0

Cough			
subjects affected / exposed	3 / 13 (23.08%)	4 / 6 (66.67%)	1 / 6 (16.67%)
occurrences (all)	3	6	2
Epistaxis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	3 / 13 (23.08%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Nasal congestion			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hypoxia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Productive cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Delirium			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ammonia increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Blood albumin decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			

subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Platelet count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis radiation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Wound			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cranial nerve disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Diabetic neuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	2
Hemiparesis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myasthenia gravis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 13 (23.08%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	3	1	2
Iron deficiency anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anaemia of malignant disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Leukopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Leukocytosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Normocytic anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 13 (7.69%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Abdominal distension			

subjects affected / exposed	1 / 13 (7.69%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 13 (7.69%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 13 (15.38%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
Dry mouth			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	3 / 13 (23.08%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	3	1	3
Gastritis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ileus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Mouth ulceration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Melaena			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 13 (23.08%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Jaundice subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Portal vein thrombosis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Liver disorder subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Skin and subcutaneous tissue disorders			
Decubitus ulcer subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Dermatitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Drug eruption subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Ecchymosis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Hidradenitis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Psoriasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Rash pruritic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vitiligo			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Incontinence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pollakiuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	4	2	0
Bone pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 13 (15.38%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
Bursitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal discomfort			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Myositis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Polyarthrititis			

subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Periarthritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aerococcus urinae infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Cystitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Dermatophytosis of nail			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatitis B reactivation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oral fungal infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Pneumonia aspiration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Upper aerodigestive tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Urinary tract infection			
subjects affected / exposed	2 / 13 (15.38%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Decreased appetite			
subjects affected / exposed	2 / 13 (15.38%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	2	1	2

Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	3	1	1
Hyperkalaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1

Hypocalcaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	4
Hypoglycaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypovitaminosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypouricaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Vitamin B12 deficiency			
subjects affected / exposed	1 / 13 (7.69%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ib Dose Escalation: MBG453 240mg Q2W + PDR001 240mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 80mg Q2W	Phase Ib Dose Escalation: MBG453 800mg Q2W + PDR001 240mg Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	5 / 5 (100.00%)	6 / 6 (100.00%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Intracranial tumour haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour invasion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 5 (40.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	4	1	2
Chest discomfort			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Catheter site pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Axillary pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Early satiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 5 (40.00%)	2 / 5 (40.00%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
Generalised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperpyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	2 / 5 (40.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Injection site reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Oedema			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Vascular device occlusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Contrast media allergy subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Social circumstances Menopause subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Menstruation irregular subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Pelvic discomfort subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Vaginal odour			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 5 (0.00%)	3 / 5 (60.00%)	0 / 6 (0.00%)
occurrences (all)	0	5	0
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			
subjects affected / exposed	1 / 5 (20.00%)	3 / 5 (60.00%)	0 / 6 (0.00%)
occurrences (all)	1	3	0
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	2
Ammonia increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Aspartate aminotransferase			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	2 / 5 (40.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Blood albumin decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Blood calcium increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	1 / 6 (16.67%) 1
Weight increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Injury, poisoning and procedural complications			
Alcohol poisoning subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Gastroenteritis radiation subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Post procedural discomfort subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Skin laceration subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Procedural pain			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	1 / 6 (16.67%) 1
Radiation skin injury subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Cardiac disorders Atrial thrombosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Nervous system disorders Balance disorder subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Ataxia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Aphasia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cranial nerve disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diabetic neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Facial paresis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hemiparesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myasthenia gravis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0

Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Anaemia of malignant disease subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Leukopenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Neutrophilia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Normocytic anaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Ear and labyrinth disorders Ear discomfort			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Vision blurred subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Anal haemorrhage subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0
Anal incontinence subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Cheilitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Dyspepsia			

subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	2 / 6 (33.33%)
occurrences (all)	1	1	3
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			

Cholangitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertransaminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Liver disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Psoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	2 / 5 (40.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Rash pruritic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Chromaturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Strangury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypopituitarism			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 5 (40.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	3 / 5 (60.00%)	2 / 6 (33.33%)
occurrences (all)	0	3	2
Bursitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myositis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Polyarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aerococcus urinae infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatitis B reactivation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Kidney infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper aerodigestive tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	2 / 5 (40.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Vaginal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hyperphosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypovitaminosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypouricaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Iron deficiency subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0

Non-serious adverse events	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 80mg Q4W	Phase Ib Dose Escalation: MBG453 80mg Q4W + PDR001 400mg Q4W	Phase II: MBG453 + PDR001 Melanoma
Total subjects affected by non-serious adverse events subjects affected / exposed	6 / 6 (100.00%)	3 / 3 (100.00%)	15 / 16 (93.75%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Cancer pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Intracranial tumour haemorrhage subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Tumour haemorrhage subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Tumour invasion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	1 / 16 (6.25%) 1
Tumour associated fever subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Vascular disorders Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 3 (33.33%) 1	0 / 16 (0.00%) 0
Embolism			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 16 (6.25%)
occurrences (all)	0	1	2
Chest discomfort			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Early satiety			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	5 / 16 (31.25%)
occurrences (all)	2	1	4
Generalised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperpyrexia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Swelling			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	1 / 16 (6.25%) 2
Pyrexia subjects affected / exposed occurrences (all)	4 / 6 (66.67%) 4	1 / 3 (33.33%) 1	2 / 16 (12.50%) 2
Vascular device occlusion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Xerosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Immune system disorders Contrast media allergy subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Social circumstances Menopause subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Menstruation irregular			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Pelvic discomfort			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Vaginal discharge			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Vaginal odour			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	3 / 16 (18.75%)
occurrences (all)	2	0	4
Epistaxis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	1
Nasal congestion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Oropharyngeal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Paranasal sinus discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Respiratory tract congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	3
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Ammonia increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Blood albumin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Body temperature increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Platelet count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis radiation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cranial nerve disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diabetic neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	1
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Myasthenia gravis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	3
Peripheral motor neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Speech disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Sciatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 3 (66.67%)	4 / 16 (25.00%)
occurrences (all)	1	2	3
Iron deficiency anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anaemia of malignant disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Normocytic anaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 6 (50.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	5	0	1
Abdominal distension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	1

Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	3 / 6 (50.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	4	0	1
Dry mouth			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	1 / 16 (6.25%)
occurrences (all)	5	1	1
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	0

Gingival pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	5 / 16 (31.25%)
occurrences (all)	4	1	6
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Rectal tenesmus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	3 / 6 (50.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	5	0	1
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	3 / 16 (18.75%)
occurrences (all)	5	1	3
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypertransaminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Liver disorder			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 16 (0.00%) 0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	1	0	2
Psoriasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Rash erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	2	0	2
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Skin hyperpigmentation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Skin mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Vitiligo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	1
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Bone cyst			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Bursitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Fracture pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Gouty arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Myositis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Polyarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Spinal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aerococcus urinae infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Eye infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Hepatitis B reactivation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Infected cyst			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Kidney infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Lip infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oral herpes			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper aerodigestive tract infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	3 / 16 (18.75%)
occurrences (all)	1	1	2
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Diabetes mellitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hypovitaminosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypouricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Vitamin B12 deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 240mg Q4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 400mg Q4W	Phase Ib Dose Escalation: MBG453 800mg Q4W + PDR001 400mg Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	6 / 7 (85.71%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Intracranial tumour haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tumour invasion			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Peripheral embolism subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Venous thrombosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Chest discomfort subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Catheter site pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Axillary pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Early satiety subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Face oedema subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Facial pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Feeling cold			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 5 (60.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	3	2	1
Generalised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperpyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vascular device occlusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Social circumstances			
Menopause			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal odour			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	2	0

Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ammonia increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	0 / 6 (0.00%)
occurrences (all)	0	6	0
Blood albumin decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hepatic enzyme increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			

subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Liver function test increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Low density lipoprotein increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Platelet count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Alcohol poisoning			

subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Gastroenteritis radiation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post procedural discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cranial nerve disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diabetic neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 5 (40.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Hemiparesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myasthenia gravis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Polyneuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anaemia of malignant disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Normocytic anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Thrombocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	3 / 6 (50.00%)
occurrences (all)	0	2	5
Abdominal distension			

subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	2 / 6 (33.33%)
occurrences (all)	3	0	3
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Gastritis			

subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Melaena			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0
Jaundice subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Portal vein thrombosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Liver disorder subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Skin and subcutaneous tissue disorders			
Decubitus ulcer subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Dermatitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Drug eruption subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	2 / 7 (28.57%) 2	0 / 6 (0.00%) 0
Ecchymosis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Hidradenitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	2 / 6 (33.33%)
occurrences (all)	0	2	3
Psoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rash erythematous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			

subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin irritation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Chromaturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	2 / 5 (40.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hypopituitarism			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Bursitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Myositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	2 / 5 (40.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Polyarthrititis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aerococcus urinae infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatitis B reactivation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oral fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper aerodigestive tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Vaginal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 5 (40.00%)	0 / 7 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	2

Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Folate deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	0 / 6 (0.00%)
occurrences (all)	0	5	0

Hypocalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	2 / 6 (33.33%)
occurrences (all)	0	3	3
Hypovitaminosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypouricaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	3	1
Vitamin B12 deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase II: MBG453 + PDR001 NSCLC	Phase Ib Dose Escalation: MBG453 1200mg Q4W + PDR001 400mgQ4W	Phase Ib Dose Escalation: MBG453 240mg Q4W + PDR001 80mg Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 17 (100.00%)	6 / 6 (100.00%)	11 / 12 (91.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Cancer pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Intracranial tumour haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tumour invasion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypotension			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 17 (11.76%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Chest discomfort			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	1 / 17 (5.88%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Early satiety			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Facial pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 17 (17.65%)	1 / 6 (16.67%)	3 / 12 (25.00%)
occurrences (all)	3	1	2
Generalised oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperpyrexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	2 / 17 (11.76%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Peripheral swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	4 / 17 (23.53%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	4	1	0
Vascular device occlusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Contrast media allergy subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Social circumstances Menopause subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Menstruation irregular subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Pelvic discomfort subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Vaginal odour			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 17 (17.65%)	1 / 6 (16.67%)	3 / 12 (25.00%)
occurrences (all)	4	1	4
Epistaxis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	3 / 17 (17.65%)	1 / 6 (16.67%)	1 / 12 (8.33%)
occurrences (all)	3	1	1
Nasal congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Hypoxia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	2 / 17 (11.76%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Paranasal sinus discomfort			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Rhinorrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 17 (11.76%)	1 / 6 (16.67%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Ammonia increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 17 (5.88%)	1 / 6 (16.67%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Blood albumin decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood calcium increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood creatine increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 17 (5.88%)	1 / 6 (16.67%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Blood potassium decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Body temperature increased			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Liver function test increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	0
Platelet count increased			

subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	1 / 12 (8.33%) 1
Weight increased subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Injury, poisoning and procedural complications			
Alcohol poisoning subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 6 (16.67%) 0	0 / 12 (0.00%) 0
Gastroenteritis radiation subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Post procedural discomfort subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Skin laceration subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Procedural pain			

subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	1 / 12 (8.33%) 1
Radiation skin injury subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Cardiac disorders Atrial thrombosis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 2	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Nervous system disorders Balance disorder subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Ataxia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Aphasia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cranial nerve disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Diabetic neuropathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic encephalopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Myasthenia gravis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 17 (23.53%)	2 / 6 (33.33%)	2 / 12 (16.67%)
occurrences (all)	6	2	2

Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Anaemia of malignant disease subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Leukopenia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 6 (16.67%) 1	0 / 12 (0.00%) 0
Neutrophilia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Normocytic anaemia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 6 (16.67%) 1	0 / 12 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Ear and labyrinth disorders Ear discomfort			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye paraesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Vision blurred subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	3 / 17 (17.65%) 3	0 / 6 (0.00%) 0	1 / 12 (8.33%) 1
Abdominal distension subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	1 / 12 (8.33%) 2
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 6 (16.67%) 1	0 / 12 (0.00%) 0
Anal haemorrhage subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Anal incontinence subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Cheilitis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Dyspepsia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	3 / 17 (17.65%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Dry mouth			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	5 / 17 (29.41%)	0 / 6 (0.00%)	4 / 12 (33.33%)
occurrences (all)	5	0	4
Gastritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 17 (17.65%)	0 / 6 (0.00%)	2 / 12 (16.67%)
occurrences (all)	3	0	2
Mouth ulceration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	0
Toothache			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 17 (11.76%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	0
Hepatobiliary disorders			

Cholangitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	0
Hypertransaminaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Liver disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Drug eruption			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Ecchymosis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hidradenitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lichenoid keratosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 17 (5.88%)	2 / 6 (33.33%)	2 / 12 (16.67%)
occurrences (all)	1	2	2
Psoriasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rash			

subjects affected / exposed	0 / 17 (0.00%)	2 / 6 (33.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Rash pruritic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rash vesicular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Haematuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Renal disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Strangury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cushing's syndrome			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hyperthyroidism			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Hypothyroidism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 17 (23.53%)	2 / 6 (33.33%)	2 / 12 (16.67%)
occurrences (all)	4	2	3
Bone pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 17 (11.76%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Bursitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Coccydynia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flank pain			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypercreatinaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 17 (5.88%)	1 / 6 (16.67%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Myalgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myositis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Polyarthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Sacral pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Spinal stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aerococcus urinae infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatitis B reactivation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 17 (0.00%)	2 / 6 (33.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Influenza			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Infected cyst			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Kidney infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Mucosal infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Rhinitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper aerodigestive tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Viral rhinitis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Dehydration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Diabetes mellitus			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Folate deficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Hyperphosphataemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 6 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypovitaminosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypouricaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1

Vitamin B12 deficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 October 2015	This amendment addressed the following revisions requested by a regulatory authority: <ul style="list-style-type: none">• Clarification in protocol to require discontinuation of study drug for Grade 3 treatment-related cardiac adverse events and for grade 3 treatment-related neurological events.• To include assessment of vital signs during infusion of study drug as well as after. In addition, include requirements to observe subjects for 1-2 hours post infusion of study drug.• Clarification of wording in protocol to provide additional details concerning dose escalation decision and number of subjects to include in the first cohort.
06 June 2016	The main purpose of this amendment was to include a Japanese dose escalation part for single-agent sabatolimab with the goal of informing subsequent clinical development opportunities in Japan.
18 July 2016	The purpose of this amendment was to update the exclusion criterion 2 as requested by a regulatory authority. The exclusion criterion was modified to clarify that subjects with a history of hypersensitivity to any ingredient of the study drugs are also excluded.
04 September 2018	The purpose of this amendment was to incorporate health authority-requested language requiring study treatment discontinuation in the event of Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN).
04 November 2019	The main purpose of this amendment was to explore a new treatment arm of sabatolimab in combination with decitabine with the option, at disease progression, to add spartalizumab in anti-PD-1/PD-L1 therapy naïve small cell lung cancer (SCLC) subjects who have failed no more than two lines of standard chemotherapy including topotecan.
31 August 2020	<p>The main purpose of this amendment is to communicate the decision by Novartis to not open enrolment in the SCLC arm for Sabatolimab in combination with decitabine. Importantly, this decision is made due to the rapidly evolving treatment landscape for SCLC patients and is not a consequence of any safety concern.</p> <p>In addition, the definition of end of study was revised to include the option for patients still on study treatment and who, in the opinion of the investigator, are still deriving clinical benefit at the time of end of study, to transfer to another study or to an alternative treatment option to continue providing study treatment to these patients.</p> <p>The objective/endpoint to assess the pharmacodynamic effect of Sabatolimab as a single agent or Sabatolimab in combination with Spartalizumab or in combination with decitabine in tumor samples using RNA/protein was switched from a secondary to an exploratory objective/endpoint as this objective was hypothesis-generating only.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/#/>

Notes: