Clinical trial results:
A Phase 1 / 2 Open Label, Multi-Arm, Multicenter Study of MK-1308 in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

Summary

EudraCT number	2019-003703-35
Trial protocol	PL GR IT
Global end of trial date	08 April 2024

Results information

Result version number	v1 (current)
This version publication date	06 April 2025
First version publication date	06 April 2025

Trial information

Trial identification

Sponsor protocol code	MK-1308-001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	126 East Lincoln Avenue, P.O. Box 2000, Rahway, NJ, United States, 07065
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.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	08 April 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 April 2024
Global end of trial reached?	Yes
Global end of trial date	08 April 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study assessed the safety, tolerability, pharmacokinetics (PK), and preliminary efficacy of escalating doses of quavonlimab when used in combination with pembrolizumab in participants with advanced solid tumors.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 July 2017
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	Australia: 43
Country: Number of subjects enrolled	Canada: 9
Country: Number of subjects enrolled	Chile: 5
Country: Number of subjects enrolled	China: 20
Country: Number of subjects enrolled	France: 19
Country: Number of subjects enrolled	Greece: 13
Country: Number of subjects enrolled	Israel: 66
Country: Number of subjects enrolled	Italy: 11
Country: Number of subjects enrolled	Japan: 17
Country: Number of subjects enrolled	Korea, Republic of: 89
Country: Number of subjects enrolled	New Zealand: 25
Country: Number of subjects enrolled	Poland: 18
Country: Number of subjects enrolled	Spain: 23
Country: Number of subjects enrolled	United States: 57
Worldwide total number of subjects	415
EEA total number of subjects	84

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)	208
From 65 to 84 years	205
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 53 centers in 16 countries

Pre-assignment

Screening details:

Per protocol, participants who showed blinded independent central review (BICR) - verified radiographical-progressive disease in Arm G were eligible to crossover to combination arm (MK-1308 25 mg + Pembrolizumab 400 mg Switchover) upon consultation with the Sponsor.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W

Arm description:

On cycle 1, day 1 of the dose escalation phase, participants with advanced solid tumors received 25 mg quavonlimab (MK-1308) monotherapy followed by 25 mg quavonlimab in combination with 200 mg pembrolizumab (pembro) every 3 weeks (Q3W) for cycles 2-5. Participants then received 200 mg pembrolizumab monotherapy Q3W starting on Cycle 6, for up to 35 cycles total (up to approximately 24 months).

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W for 24 months

Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

25 mg every 3 weeks (Q3W) for 24 months

Arm title	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W

Arm description:

On cycle 1, day 1 of the dose escalation phase, participants with advanced solid tumor except non–small cell lung cancer (NSCLC) received 75 mg quavonlimab monotherapy followed by 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W for cycles 2-5. Participants then received 200 mg pembrolizumab monotherapy Q3W starting on Cycle 6, for up to 35 cycles total (up to approximately 24 months).

Arm type	Experimental

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W for 24 months

Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

75 mg Q3W for 24 months

Arm title	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W

Arm description:

On cycle 1, day 1 of the dose escalation phase, participants with advanced solid tumor except non–small cell lung cancer (NSCLC) received 200 mg quavonlimab monotherapy followed by 200 mg quavonlimab in combination with 200 mg pembrolizumab Q3W for cycles 2-5. Participants then received 200 mg pembrolizumab monotherapy Q3W starting on Cycle 6, for up to 35 cycles total (up to approximately 24 months).

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W for 24 months

Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W for 24 months

Arm title	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W

Arm description:

On cycle 1, day 1 of the dose confirmation phase and during all subsequent cycles, participants with advanced/metastatic NSCLC received 25 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. Participants were treated for 35 cycles total (up to approximately 24 months).

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W for 24 months

Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion

Routes of administration	Intravenous use

Dosage and administration details:

25 mg Q3W for 24 months

Arm title	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W

Arm description:

On cycle 1, day 1 of the dose confirmation phase, participants with advanced/metastatic NSCLC received 25 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. On all subsequent cycles, participants received 200 mg pembrolizumab Q3W and 25 mg quavonlimab every 6 weeks (Q6W). Participants were treated for up to 35 cycles total (up to approximately 24 months).

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W for 24 months

Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

25 mg Q6W for 24 months

Arm title	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W

Arm description:

On cycle 1, day 1 of the dose confirmation phase, participants with advanced/metastatic NSCLC received 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. On all subsequent cycles, participants received 200 mg pembrolizumab Q3W and 75 mg quavonlimab Q6W. Participants were treated for 35 cycles total (up to approximately 24 months).

Arm type	Experimental
Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

75 mg Q6W for 24 months

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W for 24 months

Arm title	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W

Arm description:

On cycle 1, day 1 of the dose confirmation phase, participants with advanced/metastatic small cell lung cancer (SCLC) received 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. On all subsequent cycles, participants received 200 mg pembrolizumab Q3W and 75 mg quavonlimab Q6W. Participants were treated for 35 cycles total (up to approximately 24 months).

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W for 24 months

Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

75 mg Q6W for 24 months

Arm title	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W

Arm description:

On cycle 1, day 1 of the dose confirmation phase and during all subsequent cycles, participants with NSCLC received 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. Participants were treated for 35 cycles total (up to approximately 24 months).

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg Q3W for 24 months

Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

75 mg Q3W for 24 months

Arm title	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin

Arm description:

On cycle 1, day 1 of the efficacy expansion phase and during all subsequent cycles, participants with programmed cell death protein 1 (PD-1)/programmed cell death ligand 1 (PD-L1) refractory melanoma received 25 mg quavonlimab in combination with 400 mg pembrolizumab. Both quavonlimab and pembrolizumab were administered Q6W for 24 months.

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

400 mg Q6W for 24 months

Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab

Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

25 mg Q6W for 24 months

Arm title	Arm G: MK-1308 25 mg Q6W

Arm description:

On cycle 1, day 1 of the efficacy expansion phase and during all subsequent cycles, participants with PD-1/PD-L1 refractory melanoma received 25 mg quavonlimab Q6W for up to 24 months.

Arm type	Experimental
Investigational medicinal product name	MK-1308
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

25 mg Q6W for 24 months

Arm title	Arm I: MK-1308A Q6W (Co-form)

Arm description:

On cycle 1, day 1 of the coformulation (Co-form) phase and during all subsequent cycles, participants with advanced/metastatic solid tumors received 400 mg pembrolizumab co-formulated with 25 mg quavonlimab (MK-1308A) Q6W for 24 months.

Arm type	Experimental
Investigational medicinal product name	MK-1308A
Investigational medicinal product code	
Other name	Quavonlimab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

25 mg Q6W for 24 months

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

400 mg Q6W for 24 months

Arm title	Arm K: MK-1308A Q6W (Co-form)

Arm description:

On cycle 1, day 1 of the coformulation phase and during all subsequent cycles, participants in mainland China with advanced/metastatic solid tumors received 400 mg pembrolizumab co-formulated with 25 mg quavonlimab (MK-1308A) Q6W for 24 months.

Arm type	Experimental
Investigational medicinal product name	MK-1308A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

25 mg Q6W for 24 months

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

400 mg Q6W for 24 months

Number of subjects in period 1	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W
Started	14	18	8
Switched over to combination treatment	0	0	0
Treated	14	17	8
Completed	0	0	0
Not completed	14	18	8
Death	12	17	7
Randomized by mistake without Study Treatment	-	1	-
Withdrawal by Parent/Guardian	-	-	-
Withdrawal by Subject	1	-	-
Sponsor Decision	-	-	1
Lost to follow-up	1	-	-

Number of subjects in period 1	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W
Started	40	40	41
Switched over to combination treatment	0	0	0
Treated	40	40	40
Completed	0	0	0
Not completed	40	40	41
Death	32	29	30
Randomized by mistake without Study Treatment	-	-	1
Withdrawal by Parent/Guardian	-	-	-
Withdrawal by Subject	4	2	2
Sponsor Decision	3	9	7
Lost to follow-up	1	-	1

Number of subjects in period 1	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin
Started	40	14	111
Switched over to combination treatment	0	0	0

Treated	40	14	111
Completed	0	0	0
Not completed	40	14	111
Death	33	9	84
Randomized by mistake without Study Treatment	-	-	-
Withdrawal by Parent/Guardian	-	1	-
Withdrawal by Subject	5	-	3
Sponsor Decision	2	4	23
Lost to follow-up	-	-	1

Number of subjects in period 1	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)
Started	40	29	20
Switched over to combination treatment	21	0	0
Treated	40	29	20
Completed	0	0	0
Not completed	40	29	20
Death	33	22	15
Randomized by mistake without Study Treatment	-	-	-
Withdrawal by Parent/Guardian	-	-	-
Withdrawal by Subject	-	-	-
Sponsor Decision	6	7	5
Lost to follow-up	1	-	-

Reporting groups

Reporting group title	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose escalation phase, participants with advanced solid tumors received 25 mg quavonlimab (MK-1308) monotherapy followed by 25 mg quavonlimab in combination with 200 mg pembrolizumab (pembro) every 3 weeks (Q3W) for cycles 2-5. Participants then received 200 mg pembrolizumab monotherapy Q3W starting on Cycle 6, for up to 35 cycles total (up to approximately 24 months).

Reporting group title	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose escalation phase, participants with advanced solid tumor except non–small cell lung cancer (NSCLC) received 75 mg quavonlimab monotherapy followed by 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W for cycles 2-5. Participants then received 200 mg pembrolizumab monotherapy Q3W starting on Cycle 6, for up to 35 cycles total (up to approximately 24 months).

Reporting group title	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose escalation phase, participants with advanced solid tumor except non–small cell lung cancer (NSCLC) received 200 mg quavonlimab monotherapy followed by 200 mg quavonlimab in combination with 200 mg pembrolizumab Q3W for cycles 2-5. Participants then received 200 mg pembrolizumab monotherapy Q3W starting on Cycle 6, for up to 35 cycles total (up to approximately 24 months).

Reporting group title	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase and during all subsequent cycles, participants with advanced/metastatic NSCLC received 25 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. Participants were treated for 35 cycles total (up to approximately 24 months).

Reporting group title	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase, participants with advanced/metastatic NSCLC received 25 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. On all subsequent cycles, participants received 200 mg pembrolizumab Q3W and 25 mg quavonlimab every 6 weeks (Q6W). Participants were treated for up to 35 cycles total (up to approximately 24 months).

Reporting group title	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase, participants with advanced/metastatic NSCLC received 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. On all subsequent cycles, participants received 200 mg pembrolizumab Q3W and 75 mg quavonlimab Q6W. Participants were treated for 35 cycles total (up to approximately 24 months).

Reporting group title	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase, participants with advanced/metastatic small cell lung cancer (SCLC) received 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. On all subsequent cycles, participants received 200 mg pembrolizumab Q3W and 75 mg quavonlimab Q6W. Participants were treated for 35 cycles total (up to approximately 24 months).

Reporting group title	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase and during all subsequent cycles, participants with NSCLC received 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. Participants were treated for 35 cycles total (up to approximately 24 months).

Reporting group title	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin

Reporting group description:

On cycle 1, day 1 of the efficacy expansion phase and during all subsequent cycles, participants with programmed cell death protein 1 (PD-1)/programmed cell death ligand 1 (PD-L1) refractory melanoma received 25 mg quavonlimab in combination with 400 mg pembrolizumab. Both quavonlimab and pembrolizumab were administered Q6W for 24 months.

Reporting group title	Arm G: MK-1308 25 mg Q6W

Reporting group description:

On cycle 1, day 1 of the efficacy expansion phase and during all subsequent cycles, participants with PD-1/PD-L1 refractory melanoma received 25 mg quavonlimab Q6W for up to 24 months.

Reporting group title	Arm I: MK-1308A Q6W (Co-form)

Reporting group description:

On cycle 1, day 1 of the coformulation (Co-form) phase and during all subsequent cycles, participants with advanced/metastatic solid tumors received 400 mg pembrolizumab co-formulated with 25 mg quavonlimab (MK-1308A) Q6W for 24 months.

Reporting group title	Arm K: MK-1308A Q6W (Co-form)

Reporting group description:

On cycle 1, day 1 of the coformulation phase and during all subsequent cycles, participants in mainland China with advanced/metastatic solid tumors received 400 mg pembrolizumab co-formulated with 25 mg quavonlimab (MK-1308A) Q6W for 24 months.

Reporting group values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W
Number of subjects	14	18	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)	8	12	2
From 65-84 years	6	6	6
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	57.1	57.6	66.8
standard deviation	± 15.4	± 11.3	± 3.2
Gender Categorical			
Units: Subjects			
Female	11	10	4
Male	3	8	4
Race			
Units: Subjects			
Asian	0	0	0
Black Or African American	0	1	0
Native Hawaiian Or Other Pacific Islander	0	0	0
White	14	17	8
Missing	0	0	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	1	1	1
Not Hispanic or Latino	13	17	7

Not Reported	0	0	0
Unknown	0	0	0

Reporting group values	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W
Number of subjects	40	40	41
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)	23	18	17
From 65-84 years	17	21	24
85 years and over	0	1	0
Age Continuous Units: years			
arithmetic mean	64.2	63.7	66.3
standard deviation	± 10.9	± 11.4	± 9.2
Gender Categorical Units: Subjects			
Female	10	12	17
Male	30	28	24
Race Units: Subjects			
Asian	30	26	26
Black Or African American	0	0	1
Native Hawaiian Or Other Pacific Islander	0	0	0
White	10	14	14
Missing	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	3	0
Not Hispanic or Latino	40	37	41
Not Reported	0	0	0
Unknown	0	0	0

Reporting group values	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin
Number of subjects	40	14	111
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)	17	4	53
From 65-84 years	23	10	57
85 years and over	0	0	1
Age Continuous			
Units: years			
arithmetic mean	64.1	68.0	63.5
standard deviation	± 8.3	± 11.5	± 12.6
Gender Categorical			
Units: Subjects			
Female	16	5	34
Male	24	9	77
Race			
Units: Subjects			
Asian	16	8	3
Black Or African American	1	0	0
Native Hawaiian Or Other Pacific Islander	0	0	0
White	23	6	105
Missing	0	0	3
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	39	13	102
Not Reported	0	1	6
Unknown	1	0	2

Reporting group values	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)
Number of subjects	40	29	20
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)	24	16	14
From 65-84 years	16	13	6
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	59.7	63.7	56.6
standard deviation	± 11.6	± 11.5	± 11.9
Gender Categorical			
Units: Subjects			
Female	18	13	8

Male	22	16	12

Race Units: Subjects			
Asian	0	3	20
Black Or African American	0	0	0
Native Hawaiian Or Other Pacific Islander	0	3	0
White	38	23	0
Missing	2	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	4	0	0
Not Hispanic or Latino	33	29	20
Not Reported	2	0	0
Unknown	1	0	0

Reporting group values	Total		
Number of subjects	415		
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)	208		
From 65-84 years	205		
85 years and over	2		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical Units: Subjects			
Female	158		
Male	257		
Race Units: Subjects			
Asian	132		
Black Or African American	3		
Native Hawaiian Or Other Pacific Islander	3		
White	272		
Missing	5		
Ethnicity Units: Subjects			
Hispanic or Latino	11		

Not Hispanic or Latino	391		
Not Reported	9		
Unknown	4		

End points

End points reporting groups

Reporting group title	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose escalation phase, participants with advanced solid tumors received 25 mg quavonlimab (MK-1308) monotherapy followed by 25 mg quavonlimab in combination with 200 mg pembrolizumab (pembro) every 3 weeks (Q3W) for cycles 2-5. Participants then received 200 mg pembrolizumab monotherapy Q3W starting on Cycle 6, for up to 35 cycles total (up to approximately 24 months).

Reporting group title	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose escalation phase, participants with advanced solid tumor except non–small cell lung cancer (NSCLC) received 75 mg quavonlimab monotherapy followed by 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W for cycles 2-5. Participants then received 200 mg pembrolizumab monotherapy Q3W starting on Cycle 6, for up to 35 cycles total (up to approximately 24 months).

Reporting group title	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose escalation phase, participants with advanced solid tumor except non–small cell lung cancer (NSCLC) received 200 mg quavonlimab monotherapy followed by 200 mg quavonlimab in combination with 200 mg pembrolizumab Q3W for cycles 2-5. Participants then received 200 mg pembrolizumab monotherapy Q3W starting on Cycle 6, for up to 35 cycles total (up to approximately 24 months).

Reporting group title	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase and during all subsequent cycles, participants with advanced/metastatic NSCLC received 25 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. Participants were treated for 35 cycles total (up to approximately 24 months).

Reporting group title	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase, participants with advanced/metastatic NSCLC received 25 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. On all subsequent cycles, participants received 200 mg pembrolizumab Q3W and 25 mg quavonlimab every 6 weeks (Q6W). Participants were treated for up to 35 cycles total (up to approximately 24 months).

Reporting group title	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase, participants with advanced/metastatic NSCLC received 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. On all subsequent cycles, participants received 200 mg pembrolizumab Q3W and 75 mg quavonlimab Q6W. Participants were treated for 35 cycles total (up to approximately 24 months).

Reporting group title	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase, participants with advanced/metastatic small cell lung cancer (SCLC) received 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. On all subsequent cycles, participants received 200 mg pembrolizumab Q3W and 75 mg quavonlimab Q6W. Participants were treated for 35 cycles total (up to approximately 24 months).

Reporting group title	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W

Reporting group description:

On cycle 1, day 1 of the dose confirmation phase and during all subsequent cycles, participants with NSCLC received 75 mg quavonlimab in combination with 200 mg pembrolizumab Q3W. Participants were treated for 35 cycles total (up to approximately 24 months).

Reporting group title	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin

Reporting group description:

On cycle 1, day 1 of the efficacy expansion phase and during all subsequent cycles, participants with programmed cell death protein 1 (PD-1)/programmed cell death ligand 1 (PD-L1) refractory melanoma received 25 mg quavonlimab in combination with 400 mg pembrolizumab. Both quavonlimab and pembrolizumab were administered Q6W for 24 months.

Reporting group title	Arm G: MK-1308 25 mg Q6W

Reporting group description:

On cycle 1, day 1 of the efficacy expansion phase and during all subsequent cycles, participants with PD-1/PD-L1 refractory melanoma received 25 mg quavonlimab Q6W for up to 24 months.

Reporting group title	Arm I: MK-1308A Q6W (Co-form)

Reporting group description:

On cycle 1, day 1 of the coformulation (Co-form) phase and during all subsequent cycles, participants with advanced/metastatic solid tumors received 400 mg pembrolizumab co-formulated with 25 mg quavonlimab (MK-1308A) Q6W for 24 months.

Reporting group title	Arm K: MK-1308A Q6W (Co-form)

Reporting group description:

On cycle 1, day 1 of the coformulation phase and during all subsequent cycles, participants in mainland China with advanced/metastatic solid tumors received 400 mg pembrolizumab co-formulated with 25 mg quavonlimab (MK-1308A) Q6W for 24 months.

Subject analysis set title	Arm F Crossover: MK-1308 25mg Q6W + Pembro. 400mg Q6W Co-admin
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who demonstrated radiographically confirmed progressive disease in Arm G and switched over to combination therapy received 25 mg quavonlimab in combination with 400 mg pembrolizumab. Both quavonlimab and pembrolizumab were administered Q6W for 24 months.

Primary: Percentage of participants with ≥1 Dose Limiting Toxicity (DLT)

End point title	Percentage of participants with ≥1 Dose Limiting Toxicity

End point description:

DLTs include Grade (Gr)4 non-hematologic toxicity (not laboratory); Gr 4 hematologic toxicity lasting ≥7 days (except thrombocytopenia); most non-hematologic AEs ≥ Gr 3 in severity; any Gr 3 or Gr 4 non-hematologic laboratory value that requires clinically significant medical intervention, leads to hospitalization, persists for >1 week, or results in a drug-induced liver injury; Gr 3 or Gr 4 febrile neutropenia; a prolonged delay in initiating Cycle 2 or 3 of Dose Escalation or Cycle 2 of Dose Confirmation due to treatment-related toxicity; any treatment-related toxicity that causes the participant to discontinue treatment during the DLT observation period, and Gr 5 toxicity. Analysis population consists of all participants who received ≥1 dose of study treatment who finished the DLT observation period in the dose escalation and dose confirmation phase only. Per protocol, no analysis was planned for arms F, G, I, K and participants crossing over into MK-1308 25 mg and Pembrolizumab.

End point type	Primary

End point timeframe:

Up to 6 weeks

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 analyses 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: Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	15	7	40
Units: Percentage of Participants				
number (confidence interval 80%)	0.0 (0.0 to 10.9)	13.3 (4.9 to 26.6)	0.0 (0.0 to 18.2)	7.5 (3.3 to 14.0)

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	40	14
Units: Percentage of Participants				
number (confidence interval 80%)	5.0 (1.7 to 10.8)	10.0 (5.0 to 17.1)	10.0 (5.0 to 17.1)	7.1 (1.4 to 19.4)

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with ≥1 adverse event (AE)

End point title	Number of participants with ≥1 adverse event (AE)[3]

End point description:

An AE is defined as any untoward medical occurrence in a participant administered a pharmaceutical product temporally associated with the use of study treatment, whether or not considered related to the study treatment. The analysis population included all participants who received at least one dose of study intervention in the dose escalation (Cohorts 1-3), confirmation (arms A,B,C,D,E), efficacy expansion (arm F, G) and coformulation phases (arms I,K) only. Per protocol, no analysis was planned for participants crossing over into MK-1308 25 mg and Pembrolizumab. The number of participants who experienced an AE are presented.

End point type	Primary

End point timeframe:

Up to approximately 77 months

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 analyses were planned for this endpoint.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	17	8	40
Units: Participants	14	17	8	39

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	40	14
Units: Participants	38	40	38	14

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	111	40	29	20
Units: Participants	104	37	28	18

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants discontinuing study treatment due to an AE

End point title	Number of participants discontinuing study treatment due to an AE[4]

End point description:

An AE is defined as any untoward medical occurrence in a participant administered a pharmaceutical product temporally associated with the use of study treatment, whether or not considered related to the study treatment. The analysis population included all participants who received at least one dose of study intervention in the dose escalation (Cohorts 1-3), confirmation (arms A,B,C,D,E), efficacy expansion (arm F, G) and coformulation phases (arms I,K) only. Per protocol, no analysis was planned for participants crossing over into MK-1308 25 mg and Pembrolizumab. The number of participants who discontinued study treatment due to an AE are presented.

End point type	Primary

End point timeframe:

Up to approximately 26 months

Notes:

[4] - 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 analyses were planned for this endpoint.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	17	8	40
Units: Participants	1	4	3	7

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200	Arm C: MK-1308 75 mg Q6W + Pembro. 200	Arm D: MK-1308 75 mg Q6W + Pembro. 200	Arm E: MK-1308 75 mg Q3W + Pembro. 200

	mg Q3W	mg Q3W	mg Q3W	mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	40	14
Units: Participants	7	17	7	6

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	111	40	29	20
Units: Participants	14	1	4	2

Statistical analyses

No statistical analyses for this end point

Primary: Efficacy Expansion: Objective Response Rate (ORR) as assessed by blinded independent central review (BICR) based on adjusted Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1)

End point title	Efficacy Expansion: Objective Response Rate (ORR) as assessed by blinded independent central review (BICR) based on adjusted Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1)[5]

End point description:

ORR is defined as the percentage of participants with Complete Response (CR: disappearance of all target lesions) or Partial Response (PR: at least a 30% decrease in the sum of diameters of target lesions) per adjusted Response Evaluation Criteria In Solid Tumors Version 1.1 (RECIST 1.1). The percentage of participants who experience CR or PR in the concurrent randomized subset as assessed by Blinded Independent Central Review (BICR) will be presented. Per protocol, only data for arms F and G were presented for this endpoint. Analysis population consists of all participants with a baseline scan that demonstrated measurable disease and who were administered at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to approximately 72 months

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab.

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	40		
Units: Percentage of participants				
number (confidence interval 95%)	4.9 (0.6 to	2.5 (0.1 to		

16.5)	13.2)

Statistical analyses

Statistical analysis title	Difference in Percentage
Statistical analysis description:	
Comparision based on Miettinen & Nurminen method	
Comparison groups	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin v Arm G: MK-1308 25 mg Q6W
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentage
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	14.1

Secondary: Area under the plasma concentration time curve (AUC) of pembrolizumab

End point title	Area under the plasma concentration time curve (AUC) of pembrolizumab[6]

End point description:

AUC was defined as a measure of pembrolizumab exposure that was calculated as the product of plasma drug concentration and time after drug administration. AUC determined by blood samples collected pre-dose and at designated timepoints post-dose are presented. The analysis population included all participants who complied with the protocol sufficiently to ensure that their data will be likely to show the effects of treatment, according to the underlying scientific model and had available data from at least 1 dose of study intervention. Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab. AUC of pembrolizumab is presented. N = number of participants analyzed per cycle.

End point type	Secondary

End point timeframe:

At designated time points up to - Cohorts 1-3: Day 15 Cycle 3, Arms A, B, C, D, E: Day 15 Cycle 3, Arm F: Day 21 Cycle 3, Arm I: Day 21 Cycle 3, Arm K: Day 21 Cycle 3. Each cycle is 21 days.

Notes:

[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: Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14[7]	17[8]	8[9]	40[10]
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	0 (± 0)	0 (± 0)	0 (± 0)	608 (± 24.6)
Cycle 2	729 (± 18.3)	546 (± 40.5)	727 (± 24.5)	788 (± 24.7)
Cycle 3	0 (± 0)	0 (± 0)	0 (± 0)	911 (± 22.7)

Notes:

[7] - N=0 for cycle 1, N=11 for cycle 2, N=0 for cycle 3.

[8] - N=0 for cycle 1, N=8 for cycle 2, N=0 for cycle 3.

[9] - N=0 for cycle 1, N=3 for cycle 2, N=0 for cycle 3.

[10] - N=30 for cycle 1, N=30 for cycle 2, N=21 for cycle 3.

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40[11]	40[12]	40[13]	14[14]
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	620 (± 25.9)	627 (± 20.6)	642 (± 23.9)	554 (± 15.6)
Cycle 2	854 (± 19.9)	822 (± 25.0)	877 (± 28.3)	794 (± 18.0)
Cycle 3	971 (± 22.9)	944 (± 26.0)	1050 (± 20.8)	872 (± 16.3)

Notes:

[11] - N=34 for cycle 1, N=31 for cycle 2, N=27 for cycle 3.

[12] - N=27 for cycle 1, N=24 for cycle 2, N=19 for cycle 3.

[13] - N=28 for cycle 1, N=26 for cycle 2, N=15 for cycle 3.

[14] - N=9 for cycle 1, N=9 for cycle 2, N=7 for cycle 3

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111[15]	29[16]	20[17]	
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	2050 (± 33.6)	2250 (± 18.7)	1610 (± 25.0)	
Cycle 2	2370 (± 40.6)	2820 (± 29.7)	1770 (± 34.4)	
Cycle 3	2410 (± 29.5)	3410 (± 16.1)	2440 (± 39.8)	

Notes:

[15] - N=31 for cycle 1, N=18 for cycle 2, N=16 for cycle 3

[16] - N=8 for cycle 1, N=5 for cycle 2, N=2 for cycle 3

[17] - N=20 for cycle 1, N=16 for cycle 2, N=6 for cycle 3

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum concentration (Cmax) of pembrolizumab

End point title	Maximum concentration (Cmax) of pembrolizumab[18]

End point description:

Cmax was defined as the maximum concentration of pembrolizumab observed in plasma. Cmax determined by blood samples collected pre-dose and at designated timepoints post-dose are presented. The analysis population included all participants who complied with the protocol sufficiently to ensure that their data will be likely to show the effects of treatment, according to the underlying scientific model and had available data from at least 1 dose of study intervention. Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab. Cmax of pembrolizumab is presented. N = number of participants analyzed per cycle.

End point type	Secondary

End point timeframe:

At designated time points up to - Cohorts 1-3: Day 15 Cycle 3, Arms A, B, C, D, E: Day 15 Cycle 3, Arm F: Day 21 Cycle 3, Arm I: Day 21 Cycle 3, Arm K: Day 21 Cycle 3. Each cycle is 21 days.

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14[19]	17[20]	8[21]	40[22]
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	0.0 (± 0.0)	0.0 (± 0.0)	0.0 (± 0.0)	71.8 (± 24.0)
Cycle 2	79.8 (± 31.3)	82.3 (± 32.3)	78.7 (± 32.4)	82.9 (± 20.2)
Cycle 3	93.9 (± 21.0)	74.9 (± 28.1)	88.6 (± 12.2)	84.2 (± 16.9)

Notes:

[19] - N=0 for cycle 1, N=13 for cycle 2, N=10 for cycle 3.

[20] - N=0 for cycle 1, N=13 for cycle 2, N=11 for cycle 3.

[21] - N=0 for cycle 1, N=8 for cycle 2, N=3 for cycle 3.

[22] - N=39 for cycle 1, N=34 for cycle 2, N=31 for cycle 3.

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40[23]	40[24]	40[25]	14[26]
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	77.1 (± 26.7)	74.0 (± 27.8)	73.6 (± 22.3)	70.9 (± 35.3)
Cycle 2	88.2 (± 20.9)	83.9 (± 23.2)	90.4 (± 23.7)	84.8 (± 18.6)
Cycle 3	92.3 (± 27.5)	91.8 (± 21.7)	98.0 (± 27.4)	84.5 (± 13.8)

Notes:

[23] - N=40 for cycle 1, N=33 for cycle 2, N=32 for cycle 3.

[24] - N=37 for cycle 1, N=30 for cycle 2, N=28 for cycle 3.

[25] - N=39 for cycle 1, N=31 for cycle 2, N=26 for cycle 3.

[26] - N=14 for cycle 1, N=10 for cycle 2, N=8 for cycle 3.

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111[27]	29[28]	20[29]	
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	149 (± 29.1)	149 (± 23.8)	128 (± 21.9)	
Cycle 2	150 (± 28.9)	164 (± 22.8)	139 (± 20.5)	
Cycle 3	153 (± 22.1)	168 (± 22.3)	138 (± 31.1)	

Notes:

[27] - N=105 for cycle 1, N=94 for cycle 2, N=63 for cycle 3.

[28] - N=28 for cycle 1, N=21 for cycle 2, N=13 for cycle 3.

[29] - N=20 for cycle 1, N=16 for cycle 2, N=12 for cycle 3.

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum concentration (Cmin) of pembrolizumab

End point title	Minimum concentration (Cmin) of pembrolizumab[30]

End point description:

Cmin was defined as the minimum or "trough" concentration of pembrolizumab observed after its administration and just prior to the administration of a subsequent dose. Cmin determined by blood samples collected pre-dose and at designated timepoints post-dose are presented. The analysis population included all participants who complied with the protocol sufficiently to ensure that their data will be likely to show the effects of treatment, according to the underlying scientific model and had available data from at least 1 dose of study intervention. Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab. Cmin of pembrolizumab is presented. N = number of participants analyzed per cycle.

End point type	Secondary

End point timeframe:

At designated time points up to - Cohorts 1-3: Day 1 Cycle 4, Arms A, B, C, D, E: Day 15 Cycle 3, Arm F: Day 21 Cycle 3, Arm I: Day 21 Cycle 3, Arm K: Day 21 Cycle 3. Each cycle is 21 days.

Notes:

[30] - 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: Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14[31]	17[32]	8[33]	40[34]
Units: µg/mL				
median (full range (min-max))				
Cycle 1	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	13.3 (0.00 to 22.3)
Cycle 2	18.3 (11.3 to 27.8)	11.3 (0.00 to 28.1)	19.0 (9.21 to 24.6)	19.6 (6.62 to 37.4)
Cycle 3	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	25.7 (13.7 to 40.3)
Cycle 4	34.3 (29.8 to 39.9)	14.1 (0.00 to 38.1)	23.5 (23.5 to 23.5)	0.00 (0.00 to 0.00)

Notes:

[31] - N=0 for cycle 1, N=11 for cycle 2, N=0 for cycle 3, N=4 for cycle 4.

[32] - N=0 for cycle 1, N=10 for cycle 2, N=0 for cycle 3, N=5 for cycle 4.

[33] - N=0 for cycle 1, N=3 for cycle 2, N=0 for cycle 3, N=1 for cycle 4.

[34] - N=33 for cycle 1, N=31 for cycle 2, N=22 for cycle 3, N=0 for cycle 4.

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40[35]	40[36]	40[37]	14[38]
Units: µg/mL				
median (full range (min-max))				
Cycle 1	13.1 (3.93 to 24.9)	14.3 (5.59 to 90.4)	15.6 (6.35 to 35.9)	11.5 (4.77 to 18.0)
Cycle 2	24.3 (9.06 to 34.6)	20.4 (9.19 to 44.9)	25.2 (10.1 to 55.1)	18.9 (8.52 to 25.5)
Cycle 3	27.5 (12.4 to 42.2)	25.5 (11.3 to 98.2)	29.3 (10.4 to 56.7)	27.7 (14.5 to 30.5)
Cycle 4	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)

Notes:

[35] - N=35 for cycle 1, N=33 for cycle 2, N=28 for cycle 3, N=0 for cycle 4.

[36] - N=30 for cycle 1, N=28 for cycle 2, N=20 for cycle 3, N=0 for cycle 4

[37] - N=29 for cycle 1, N=28 for cycle 2, N=18 for cycle 3, N=0 for cycle 4.

[38] - N=9 for cycle 1, N=9 for cycle 2, N=7 for cycle 3, N=0 for cycle 4.

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111[39]	29[40]	20[41]	
Units: µg/mL				
median (full range (min-max))				
Cycle 1	21.9 (1.89 to 143)	19.5 (7.25 to 35.8)	14.4 (5.74 to 26.0)	

Cycle 2	23.1 (0.0266 to 51.6)	30.0 (16.2 to 60.4)	22.5 (8.74 to 37.1)	
Cycle 3	24.5 (2.22 to 127)	34.0 (18.9 to 72.2)	26.6 (7.74 to 32.6)	
Cycle 4	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	

Notes:

[39] - N=92 for cycle 1, N=63 for cycle 2, N=43 for cycle 3, N=0 for cycle 4.

[40] - N=21 for cycle 1, N=13 for cycle 2, N=9 for cycle 3, N=0 for cycle 4.

[41] - N=16 for cycle 1, N=12 for cycle 2, N=9 for cycle 3, N=0 for cycle 4.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC of quavonlimab (MK-1308)

End point title	AUC of quavonlimab (MK-1308)

End point description:

AUC was defined as a measure of quavonlimab exposure that was calculated as the product of plasma drug concentration and time after drug administration. AUC determined by blood samples collected pre-dose and at designated timepoints post-dose are presented. The analysis population included all participants who complied with the protocol sufficiently to ensure that their data will be likely to show the effects of treatment, according to the underlying scientific model and had available data from at least 1 dose of study intervention. Per protocol, no analysis was planned for participants crossing over into MK-1308 25 mg and Pembrolizumab. AUC of quavonlimab is presented. N = number of participants analyzed per cycle.

End point type	Secondary

End point timeframe:

At designated time points up to - Cohorts 1-3: Day 15 Cycle 3, Arms A, B, C, D, E: Day 15 Cycle 3, Arm F, G, I: Day 21 Cycle 3, Arm K: Day 21 Cycle 3. Each cycle is 21 days.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14[42]	17[43]	8[44]	40[45]
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	68.2 (± 17.7)	160 (± 19.5)	510 (± 25.7)	55.0 (± 26.6)
Cycle 2	91.5 (± 19.9)	178 (± 53.9)	751 (± 23.4)	73.6 (± 26.4)
Cycle 3	0.0 (± 0.0)	0.0 (± 0.0)	0.0 (± 0.0)	64.3 (± 56.5)

Notes:

[42] - N=10 for cycle 1, N=8 for cycle 2, N=0 for cycle 3.

[43] - N=13 for cycle 1, N=4 for cycle 2, N=0 for cycle 3.

[44] - N=8 for cycle 1, N=3 for cycle 2, N=0 for cycle 3.

[45] - N=26 for cycle 1, N=21 for cycle 2, N=16 for cycle 3.

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40[46]	40[47]	40[48]	14[49]
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	69.6 (± 33.5)	199 (± 36.2)	222 (± 39.7)	178 (± 17.6)
Cycle 2	0.0 (± 0.0)	0.0 (± 0.0)	0.0 (± 0.0)	192 (± 17.7)
Cycle 3	59.4 (± 74.9)	182 (± 75.1)	193 (± 90.8)	186 (± 22.1)

Notes:

[46] - N=21 for cycle 1, N=0 for cycle 2, N=20 for cycle 3.

[47] - N=28 for cycle 1, N=0 for cycle 2, N=19 for cycle 3.

[48] - N=28 for cycle 1, N=0 for cycle 2, N=16 for cycle 3.

[49] - N=10 for cycle 1, N=8 for cycle 2, N=6 for cycle 3.

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	111[50]	40[51]	29[52]	20[53]
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	77.1 (± 32.7)	92.8 (± 38.1)	106 (± 34.7)	85.8 (± 24.2)
Cycle 2	94.4 (± 43.9)	65.9 (± 27.8)	96.1 (± 39.7)	86.0 (± 47.7)
Cycle 3	95.2 (± 63.4)	95.0 (± 58.2)	72.1 (± 9.92)	92.3 (± 60.2)

Notes:

[50] - N=34 for cycle 1, N=18 for cycle 2, N=17 for cycle 3.

[51] - N=9 for cycle 1, N=4 for cycle 2, N=3 for cycle 3.

[52] - N=8 for cycle 1, N=5 for cycle 2, N=2 for cycle 3.

[53] - N=20 for cycle 1, N=14 for cycle 2, N=6 for cycle 3.

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum concentration (Cmax) of quavonlimab

End point title	Maximum concentration (Cmax) of quavonlimab

End point description:

Cmax was defined as the maximum concentration of quavonlimab observed in plasma. Cmax determined by blood samples collected pre-dose and at designated timepoints post-dose are presented. The analysis population included all participants who complied with the protocol sufficiently to ensure that their data will be likely to show the effects of treatment, according to the underlying scientific model and had available data from at least 1 dose of study intervention. Per protocol, no analysis was planned for participants crossing over into MK-1308 25 mg and Pembrolizumab. Cmax of quavonlimab is presented. N = number of participants analyzed per cycle.

End point type	Secondary

End point timeframe:

At designated time points up to - Cohorts 1-3: Day 15 Cycle 3, Arms A, B, C, D, E: Day 15 Cycle 3, Arm F, G, I: Day 21 Cycle 3, Arm K: Day 21 Cycle 3. Each cycle is 21 days.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14[54]	17[55]	8[56]	40[57]
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	8.23 (± 26.1)	22.5 (± 29.8)	68.3 (± 17.2)	7.28 (± 30.6)
Cycle 2	9.41 (± 20.4)	23.5 (± 25.1)	71.9 (± 29.0)	8.58 (± 22.4)
Cycle 3	9.11 (± 24.7)	23.3 (± 48.0)	88.3 (± 16.0)	7.72 (± 27.7)

Notes:

[54] - N=12 for cycle 1, N=13 for cycle 2, N=10 for cycle 3.

[55] - N=17 for cycle 1, N=10 for cycle 2, N=9 for cycle 3.

[56] - N=8 for cycle 1, N=7 for cycle 2, N=3 for cycle 3.

[57] - N=38 for cycle 1, N=35 for cycle 2, N=31 for cycle 3.

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40[58]	40[59]	40[60]	14[61]
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	8.02 (± 29.5)	23.4 (± 24.3)	24.1 (± 30.1)	25.0 (± 20.6)
Cycle 2	0.0 (± 0.0)	0.0 (± 0.0)	0.0 (± 0.0)	26.3 (± 24.7)
Cycle 3	6.98 (± 43.7)	22.7 (± 33.1)	24.2 (± 50.4)	27.2 (± 10.2)

Notes:

[58] - N=39 for cycle 1, N=0 for cycle 2, N=32 for cycle 3.

[59] - N=38 for cycle 1, N=0 for cycle 2, N=26 for cycle 3.

[60] - N=38 for cycle 1, N=0 for cycle 2, N=26 for cycle 3.

[61] - N=14 for cycle 1, N=10 for cycle 2, N=7 for cycle 3.

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	111[62]	40[63]	29[64]	20[65]
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1	7.25 (± 26.4)	7.42 (± 30.4)	8.06 (± 26.5)	8.23 (± 26.7)
Cycle 2	7.65 (± 25.3)	7.22 (± 29.3)	8.17 (± 26.2)	7.99 (± 29.7)
Cycle 3	7.94 (± 29.6)	6.65 (± 32.7)	7.25 (± 21.9)	7.94 (± 35.4)

Notes:

[62] - N=106 for cycle 1, N=95 for cycle 2, N=65 for cycle 3.

[63] - N=37 for cycle 1, N=33 for cycle 2, N=11 for cycle 3.

[64] - N=27 for cycle 1, N=21 for cycle 2, N=13 for cycle 3.

[65] - N=20 for cycle 1, N=16 for cycle 2, N=12 for cycle 3.

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum concentration (Cmin) of quavonlimab

End point title	Minimum concentration (Cmin) of quavonlimab

End point description:

Cmin was defined as the minimum or "trough" concentration of quavonlimab observed after its administration and just prior to the administration of a subsequent dose. Cmin determined by blood samples collected pre-dose and at designated timepoints post-dose are presented. The analysis population included all participants who complied with the protocol sufficiently to ensure that their data will be likely to show the effects of treatment, according to the underlying scientific model and had available data from at least 1 dose of study intervention. Per protocol, no analysis was planned for participants crossing over into MK-1308 25 mg and Pembrolizumab. Cmin of quavonlimab is presented. Data points listed as "0" had no participants that met per protocol criteria and were not analyzed. N = number of participants analyzed per cycle.

End point type	Secondary

End point timeframe:

At designated time points up to - Cohorts 1-3: Day 15 Cycle 3, Arms A, B, C, D, E: Day 15 Cycle 3, Arm F, G, I: Day 21 Cycle 3, Arm K: Day 21 Cycle 3. Each cycle is 21 days.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14[66]	17[67]	8[68]	40[69]
Units: µg/mL				
median (full range (min-max))				
Cycle 1	1.44 (0.00 to 2.11)	3.29 (0.00 to 6.86)	8.01 (1.51 to 17.8)	1.05 (0.00 to 1.80)
Cycle 2	1.75 (0.00 to 3.10)	2.83 (0.00 to 10.3)	17.4 (1.73 to 19.2)	1.17 (0.00 to 2.73)
Cycle 3	0.00 (0.00 to 0.00)	1.91 (1.91 to 1.91)	0.00 (0.00 to 0.00)	1.42 (0.00 to 2.86)

Notes:

[66] - N=13 for cycle 1, N=11 for cycle 2, N=0 for cycle 3.

[67] - N=14 for cycle 1, N=10 for cycle 2, N=1 for cycle 3.

[68] - N=8 for cycle 1, N=3 for cycle 2, N=0 for cycle 3.

[69] - N=35 for cycle 1, N=31 for cycle 2, N=22 for cycle 3.

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40[70]	40[71]	40[72]	14[73]
Units: µg/mL				
median (full range (min-max))				
Cycle 1	0.00 (0.00 to 0.00)	0.00 (0.00 to 3.44)	15.6 (6.35 to 35.9)	3.20 (0.00 to 5.26)
Cycle 2	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	25.2 (10.1 to 55.1)	3.40 (1.35 to 6.32)
Cycle 3	0.00 (0.00 to 0.00)	0.00 (0.00 to 3.10)	29.3 (10.4 to 56.7)	2.91 (2.21 to 5.77)

Notes:

[70] - N=33 for cycle 1, N=0 for cycle 2, N=25 for cycle 3.

[71] - N=26 for cycle 1, N=0 for cycle 2, N=21 for cycle 3.

[72] - N=29 for cycle 1, N=28 for cycle 2, N=18 for cycle 3.

[73] - N=10 for cycle 1, N=8 for cycle 2, N=6 for cycle 3.

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	111[74]	40[75]	29[76]	20[77]
Units: µg/mL				
median (full range (min-max))				
Cycle 1	0.00 (0.00 to 1.65)	0.00 (0.00 to 1.26)	0.00 (0.00 to 2.02)	0.00 (0.00 to 1.32)
Cycle 2	0.00 (0.00 to 8.23)	0.00 (0.00 to 2.09)	0.00 (0.00 to 1.68)	0.00 (0.00 to 1.65)
Cycle 3	0.00 (0.00 to 7.50)	0.00 (0.00 to 7.20)	0.00 (0.00 to 2.37)	0.00 (0.00 to 1.05)

Notes:

[74] - N=95 for cycle 1, N=62 for cycle 2, N=43 for cycle 3.

[75] - N=32 for cycle 1, N=11 for cycle 2, N=8 for cycle 3.

[76] - N=21 for cycle 1, N=13 for cycle 2, N=9 for cycle 3.

[77] - N=16 for cycle 1, N=12 for cycle 2, N=9 for cycle 3.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with pembrolizumab anti-drug antibodies (ADAs)

End point title	Number of participants with pembrolizumab anti-drug antibodies (ADAs)[78]

End point description:

Non-Treatment emergent (TE) ADA refers to presence of ADAs (as determined by assay) in the absence of treatment with pembrolizumab (i.e., at predose). Evaluable participants (used as the denominator for analysis) are the total number of negative, inconclusive, and positive participants (non-treatment emergent, treatment emergent and treatment boosted). Inconclusive participants are the number of participants with no positive ADA samples present and the drug concentration in the last sample above the drug tolerance level. ADA determined by blood samples collected pre-dose and at designated timepoints post-dose are presented. The analysis population included all participants with at least one ADA sample available after treatment with pembrolizumab. Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab. N = number of participants analyzed per cycle.

End point type	Secondary

End point timeframe:

Cohorts 1-3: Predose and day 1 of cycles 2, 3, 5, 6, 7, 9 and every 4 cycles up to 35 cycles. Arms A-E: Predose and day 1 of cycles 1-5, 6, 8 and every 4 cycles up to 35 cycles. Arms F, I, K: Predose and day 1 of cycles 1, 2, 3, 4. Each cycle is 21 days.

Notes:

[78] - 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: Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	13	5	36
Units: Participants				
number (not applicable)				
Evaluable	12	13	5	36
Negative	12	12	5	31
Non - TE Neutralizing Antibody(NAB) NEG (Negative)	0	1	0	0
TE NAB NEG	0	0	0	4
TE NAB Positive (POS)	0	0	0	1
Inconclusive	0	0	0	0
Treatment Boosted (TB) NAB NEG	0	0	0	0

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	37	35	11
Units: Participants				
number (not applicable)				
Evaluable	39	37	35	11
Negative	33	33	31	10
Non - TE Neutralizing Antibody(NAB) NEG (Negative)	0	0	0	0
TE NAB NEG	4	3	4	1
TE NAB Positive (POS)	0	1	0	0
Inconclusive	2	0	0	0
Treatment Boosted (TB) NAB NEG	0	0	0	0

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)	

	admin			
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	103	23	20	
Units: Participants				
number (not applicable)				
Evaluable	103	23	20	
Negative	94	20	13	
Non - TE Neutralizing Antibody(NAB) NEG (Negative)	0	1	0	
TE NAB NEG	3	0	2	
TE NAB Positive (POS)	0	0	1	
Inconclusive	5	2	4	
Treatment Boosted (TB) NAB NEG	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with quavonlimab anti-drug antibodies (ADAs)

End point title	Number of participants with quavonlimab anti-drug antibodies (ADAs)

End point description:

Non-Treatment emergent (TE) ADA refers to presence of ADAs (as determined by assay) in the absence of treatment with quavonlimab (i.e., at predose). Evaluable participants (used as the denominator for analysis) are the total number of negative, inconclusive, and positive participants (non-treatment emergent, treatment emergent and treatment boosted). Inconclusive participants are the number of participants with no positive ADA samples present and the drug concentration in the last sample above the drug tolerance level. ADA determined by blood samples collected pre-dose and at designated timepoints post-dose are presented. The analysis population included all participants with at least one ADA sample available after treatment with quavonlimab. Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab. N = number of participants analyzed per cycle.

End point type	Secondary

End point timeframe:

Cohort 1-3: Predose and day 1 of cycles 2, 3, 5, 6, 7, 9 and every 4 cycles up to 35 cycles. Arms A-E: Predose and day 1 of cycle 1-5, 6, 8 and every 4 cycles up to 35 cycles. Arms F, G, I, K: Predose and day 1 of cycles 1, 2, 3, 4. Each cycle is 21 days.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	8	36
Units: Participants				
number (not applicable)				
Evaluable	14	15	8	36
Negative	3	7	4	12
Non - TE Neutralizing Antibody(NAB) NEG (Negative)	0	0	0	0

TE NAB NEG	0	0	0	0
TE NAB POS	0	0	0	0
Inconclusive	0	0	0	0
TB NAB NEG	0	0	0	0
TB NAB MISSING	0	1	0	0
TE NAB MISSING	11	7	4	23
NON-TE NAB MISSING	0	0	0	1

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	37	35	11
Units: Participants				
number (not applicable)				
Evaluable	39	37	35	11
Negative	6	6	8	4
Non - TE Neutralizing Antibody(NAB) NEG (Negative)	0	0	0	0
TE NAB NEG	0	0	0	0
TE NAB POS	0	0	0	0
Inconclusive	0	0	1	0
TB NAB NEG	0	0	0	0
TB NAB MISSING	0	1	0	0
TE NAB MISSING	32	30	26	7
NON-TE NAB MISSING	1	0	0	0

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	102	38	23	20
Units: Participants				
number (not applicable)				
Evaluable	102	38	23	20
Negative	35	21	8	6
Non - TE Neutralizing Antibody(NAB) NEG (Negative)	0	0	0	0
TE NAB NEG	0	0	0	0
TE NAB POS	0	0	0	0
Inconclusive	2	1	0	1
TB NAB NEG	0	0	0	0
TB NAB MISSING	3	2	0	2
TE NAB MISSING	61	13	15	11
NON-TE NAB MISSING	1	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Escalation, Dose Confirmation, Coformulation: ORR as assessed by investigator based on adjusted RECIST v1.1

End point title	Dose Escalation, Dose Confirmation, Coformulation: ORR as assessed by investigator based on adjusted RECIST v1.1[79]

End point description:

ORR is defined as the percentage of participants with Complete Response (CR: disappearance of all target lesions) or Partial Response (PR: at least a 30% decrease in the sum of diameters of target lesions) per Response Evaluation Criteria In Solid Tumors Version 1.1 (RECIST 1.1). The percentage of participants who experience CR or PR as assessed by BICR will be presented. Per protocol, only data for Dose Escalation (Cohorts 1, 2, 3), Dose Confirmation (Arms A, B, C, D, E), Coformulation (Arms I and K) were presented for this endpoint, no analysis was planned for participants crossing over into MK-1308 25 mg and Pembrolizumab. Analysis population consists of all participants with a baseline scan that demonstrated measurable disease and who were administered at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Up to approximately 72 months

Notes:

[79] - 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: Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab.

End point values	Cohort 1: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	17	8	40
Units: Percentage				
number (confidence interval 95%)	0.0 (0.0 to 23.2)	0.0 (0.0 to 19.5)	25.0 (3.2 to 65.1)	32.5 (18.6 to 49.1)

End point values	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	40	14
Units: Percentage				
number (confidence interval 95%)	37.5 (22.7 to 54.2)	30.0 (16.6 to 46.5)	15.0 (5.7 to 29.8)	35.7 (12.8 to 64.9)

End point values	Arm I: MK-1308A Q6W (Co-form)	Arm K: MK-1308A Q6W (Co-form)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	20		
Units: Percentage				
number (confidence interval 95%)	10.3 (2.2 to 27.4)	20.0 (5.7 to 43.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Efficacy Expansion: Duration of Response (DOR) as assessed by BICR based on adjusted RECIST v1.1

End point title	Efficacy Expansion: Duration of Response (DOR) as assessed by BICR based on adjusted RECIST v1.1[80]

End point description:

DOR was defined as the time from first documented evidence of complete response (CR: Disappearance of all target lesions) or confirmed partial response (PR: At least a 30% decrease in the sum of diameters of target lesions) until progressive disease (PD) or death. Per RECIST 1.1, PD is defined as at least a 20% increase in the sum of diameters of target lesions. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered PD. DOR as assessed by Blinded Independent Central Review (BICR) will be presented. A value of 9999 = median and lower limit not reached at time of data cut-off due to insufficient number of responding participants with relapse. Per protocol, only data for arms F and G were presented for this endpoint. Analysis population consists of all participants who received at least one dose of study intervention in arms F and G who had either a CR or PR.

End point type	Secondary

End point timeframe:

Up to approximately 72 months

Notes:

[80] - 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: Per protocol, no analysis was planned for arm G and participants crossing over into MK-1308 25 mg and Pembrolizumab.

End point values	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	1		
Units: Months				
median (full range (min-max))	9999 (6.2 to 9999)	8.6 (8.6 to 8.6)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 77 months

Adverse event reporting additional description:

Analysis population for all-cause mortality consists of all allocated participants.

Analysis population for safety consists of all participants who received at least one dose of study intervention.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Cohort 1: MK-1308 25 mg Q3W+Pembro. 200 mg Q3W
Reporting group description: -	
Reporting group title	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W
Reporting group description: -	
Reporting group title	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Reporting group description: -	
Reporting group title	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W
Reporting group description: -	
Reporting group title	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W
Reporting group description: -	
Reporting group title	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Reporting group description: -	
Reporting group title	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W
Reporting group description: -	
Reporting group title	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Reporting group description: -	
Reporting group title	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin
Reporting group description: -	
Reporting group title	Arm F Crossover: MK-1308 25mg Q6W + Pembro. 400mg Q6W Co-admin
Reporting group description: -	
Reporting group title	Arm G: MK-1308 25 mg Q6W
Reporting group description: -	
Reporting group title	Arm I: MK-1308A Q6W (Co-form)
Reporting group description: -	
Reporting group title	Arm K: MK-1308A Q6W (Co-form)

Reporting group description: -

Serious adverse events	Cohort 1: MK-1308 25 mg Q3W+Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Total subjects affected by serious adverse events			

subjects affected / exposed	2 / 14 (14.29%)	4 / 8 (50.00%)	20 / 40 (50.00%)
number of deaths (all causes)	13	7	33
number of deaths resulting from adverse events	0	0	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bowen's disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine tumour			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (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
Incarcerated hernia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Malaise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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			
Atelectasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	5 / 40 (12.50%)
occurrences causally related to treatment / all	0 / 0	1 / 1	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	2 / 2
Pulmonary embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
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			
Animal bite			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation oesophagitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 arrest			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coronary artery disease			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachyarrhythmia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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			
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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%)	1 / 8 (12.50%)	0 / 40 (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
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric lymphadenitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vestibular disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (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
Colitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diverticular perforation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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			
Autoimmune hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (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
Haematuria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (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
Nephritis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 obstruction			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (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
Urinoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteolysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (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
Bronchopulmonary aspergillosis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
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 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			

subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 40 (35.00%)	23 / 40 (57.50%)	10 / 17 (58.82%)
number of deaths (all causes)	31	32	17
number of deaths resulting from adverse events	1	7	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bowen's disease			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (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 / 40 (0.00%)	0 / 40 (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 central nervous system			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Neuroendocrine tumour			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Paraneoplastic syndrome			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Tumour pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Embolism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (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
Chest pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Death			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0

Fatigue			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Incarcerated hernia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Malaise			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (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			
Atelectasis			

subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Haemoptysis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Dyspnoea			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Lung disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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	2 / 40 (5.00%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 17 (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
Pneumonitis			
subjects affected / exposed	4 / 40 (10.00%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	4 / 4	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Delirium			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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			
Animal bite			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Radiation oesophagitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Subdural haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Atrial fibrillation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Atrioventricular block complete			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Cardiac arrest			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Cardiac failure			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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

Cardiac failure congestive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Coronary artery disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Tachyarrhythmia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Pericarditis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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			
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Brain oedema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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

Cerebral infarction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Cerebral haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Guillain-Barre syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Autoimmune haemolytic anaemia			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Febrile neutropenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Mesenteric lymphadenitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Ear and labyrinth disorders			
Vestibular disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Colitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	1 / 40 (2.50%)	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
Diarrhoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Diverticular perforation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Enterocolitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Large intestine perforation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Nausea			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Rectal haemorrhage			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Oesophagitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Subileus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Biliary obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Cholecystitis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Cholelithiasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Hypertransaminasaemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (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
Immune-mediated hepatitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (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
Cholestasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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			
Rash			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 lesion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Nephritis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Urinoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Hyperthyroidism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Hypophysitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (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
Hypothyroidism			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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			
Arthritis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Back pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (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
Osteolysis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 stenosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Infections and infestations			
Appendicitis perforated			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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

Arthritis infective			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Bacteraemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Cellulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Encephalitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Herpes zoster			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Infective exacerbation of bronchiectasis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	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
Lower respiratory tract infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Meningitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 candidiasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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	4 / 40 (10.00%)	9 / 40 (22.50%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 4	2 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 0
Sepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 sepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 cord infection			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Septic shock			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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			
Dehydration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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 / 40 (0.00%)	0 / 40 (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
Hyperglycaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Hyponatraemia			

subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (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
Hyperkalaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (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

Serious adverse events	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 40 (40.00%)	10 / 14 (71.43%)	31 / 111 (27.93%)
number of deaths (all causes)	35	9	86
number of deaths resulting from adverse events	3	2	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bowen's disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (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
Neuroendocrine tumour			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (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
Fatigue			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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			

Benign prostatic hyperplasia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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			
Atelectasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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	2 / 40 (5.00%)	0 / 14 (0.00%)	0 / 111 (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
Haemoptysis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	2 / 40 (5.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (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 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			

subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation oesophagitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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			
Acute myocardial infarction			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (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
Atrial fibrillation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 arrest			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (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
Myocardial infarction			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (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
Tachyarrhythmia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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			

Autonomic nervous system imbalance			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (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
Guillain-Barre syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Seizure			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			

subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (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 / 40 (0.00%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (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
Mesenteric lymphadenitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (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
Ear and labyrinth disorders			
Vestibular disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (2.50%)	1 / 14 (7.14%)	4 / 111 (3.60%)
occurrences causally related to treatment / all	1 / 1	0 / 1	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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	1 / 40 (2.50%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Large intestinal obstruction			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (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
Oesophagitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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			
Autoimmune hepatitis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 lesion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	2 / 111 (1.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (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
Urinary tract obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinoma			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (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
Endocrine disorders			

Adrenal insufficiency			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	2 / 111 (1.80%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteolysis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (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

Spinal pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Encephalitis			
subjects affected / exposed	2 / 40 (5.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (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
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 candidiasis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	3 / 40 (7.50%)	3 / 14 (21.43%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Sepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 cord infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (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
Septic shock			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
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 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm F Crossover: MK-1308 25mg Q6W + Pembro. 400mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 21 (19.05%)	9 / 40 (22.50%)	15 / 29 (51.72%)
number of deaths (all causes)	17	16	22
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bowen's disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine tumour			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (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
Chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 21 (4.76%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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			
Atelectasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (4.76%)	0 / 40 (0.00%)	0 / 29 (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
Lung disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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			
Animal bite			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation oesophagitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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			
Acute myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 arrest			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachyarrhythmia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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			
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric lymphadenitis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vestibular disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (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
Colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diverticular perforation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (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
Large intestine perforation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (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
Small intestinal obstruction			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	1 / 21 (4.76%)	1 / 40 (2.50%)	0 / 29 (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
Vomiting			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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			
Autoimmune hepatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 lesion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	2 / 40 (5.00%)	0 / 29 (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
Muscular weakness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteolysis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (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
Cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 cord infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
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	Arm K: MK-1308A Q6W (Co-form)		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 20 (20.00%)		
number of deaths (all causes)	15		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bowen's disease			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cancer pain			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to central nervous system			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuroendocrine tumour			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraneoplastic syndrome			

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour pain				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Deep vein thrombosis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Asthenia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chest pain				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Death				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Fatigue				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incarcerated hernia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malaise				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Benign prostatic hyperplasia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Atelectasis				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Confusional state				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Alanine aminotransferase increased				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspartate aminotransferase increased				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Troponin increased				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radiation oesophagitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block complete			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Cardiac failure congestive				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiogenic shock				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachyarrhythmia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericarditis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Autonomic nervous system imbalance				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain oedema				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cerebral infarction				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral haematoma				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Guillain-Barre syndrome				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolic encephalopathy				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune haemolytic anaemia				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mesenteric lymphadenitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
Vestibular disorder				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Retinal detachment				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Constipation				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticular perforation				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subileus				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Autoimmune hepatitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary obstruction				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertransaminasaemia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated hepatitis				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cholestasis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Rash				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin lesion				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				

Acute kidney injury				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephritis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract obstruction				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinoma				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Adrenal insufficiency				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperthyroidism				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypophysitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypothyroidism				

subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteolysis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal pain			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal stenosis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis perforated			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Arthritis infective				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopulmonary aspergillosis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19 pneumonia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of bronchiectasis				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal candidiasis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal cord infection				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic metabolic decompensation				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Type 1 diabetes mellitus				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Type 2 diabetes mellitus				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Cohort 1: MK-1308 25 mg Q3W+Pembro. 200 mg Q3W	Cohort 3: MK-1308 200 mg Q3W + Pembro. 200 mg Q3W	Arm A: MK-1308 25 mg Q3W + Pembro. 200 mg Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)	8 / 8 (100.00%)	38 / 40 (95.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	3 / 14 (21.43%)	1 / 8 (12.50%)	1 / 40 (2.50%)
occurrences (all)	3	1	1
Tumour haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	2	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 8 (25.00%)	4 / 40 (10.00%)
occurrences (all)	0	2	5
Catheter site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Early satiety			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	7 / 14 (50.00%)	2 / 8 (25.00%)	9 / 40 (22.50%)
occurrences (all)	7	2	13
General physical health deterioration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			

subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Localised oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	4 / 40 (10.00%)
occurrences (all)	1	0	4
Oedema peripheral			
subjects affected / exposed	0 / 14 (0.00%)	2 / 8 (25.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Hypersensitivity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			

Chylothorax			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 14 (7.14%)	1 / 8 (12.50%)	5 / 40 (12.50%)
occurrences (all)	1	1	7
Dyspnoea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	7 / 40 (17.50%)
occurrences (all)	1	0	7
Hypercapnia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Hypoxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	4 / 40 (10.00%)
occurrences (all)	1	0	5
Pneumonitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Productive cough			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	3 / 40 (7.50%)
occurrences (all)	0	0	3
Wheezing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	6 / 40 (15.00%)
occurrences (all)	0	0	8
Depression			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences (all)	1	0	2
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	10 / 40 (25.00%)
occurrences (all)	0	0	12
Ammonia increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 14 (7.14%)	2 / 8 (25.00%)	9 / 40 (22.50%)
occurrences (all)	2	2	9
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 14 (14.29%)	2 / 8 (25.00%)	0 / 40 (0.00%)
occurrences (all)	2	2	0
Blood corticotrophin increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	2 / 8 (25.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
C-reactive protein increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 14 (14.29%)	2 / 8 (25.00%)	1 / 40 (2.50%)
occurrences (all)	2	2	1
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	5 / 40 (12.50%)
occurrences (all)	0	1	5
White blood cell count decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 14 (14.29%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Dental restoration failure			

subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Animal bite			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	5 / 40 (12.50%)
occurrences (all)	0	0	5
Hypoaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	7 / 40 (17.50%)
occurrences (all)	1	0	7
Neuralgia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	3 / 40 (7.50%)
occurrences (all)	0	0	4
Presyncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 14 (7.14%)	2 / 8 (25.00%)	1 / 40 (2.50%)
occurrences (all)	2	2	1
Eosinophilia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Thrombocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vision blurred			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	2 / 14 (14.29%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	3	0	1
Abdominal pain			
subjects affected / exposed	2 / 14 (14.29%)	1 / 8 (12.50%)	2 / 40 (5.00%)
occurrences (all)	2	1	2
Abdominal pain upper			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	3 / 14 (21.43%)	1 / 8 (12.50%)	4 / 40 (10.00%)
occurrences (all)	4	1	4
Dental caries			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	3 / 14 (21.43%)	3 / 8 (37.50%)	9 / 40 (22.50%)
occurrences (all)	4	3	18
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0

Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 14 (7.14%)	3 / 8 (37.50%)	10 / 40 (25.00%)
occurrences (all)	1	3	17
Obstruction gastric			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 14 (14.29%)	2 / 8 (25.00%)	5 / 40 (12.50%)
occurrences (all)	4	2	9
Small intestinal obstruction			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Hypertransaminasaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	3 / 14 (21.43%)	0 / 8 (0.00%)	5 / 40 (12.50%)
occurrences (all)	4	0	5
Rash			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	11 / 40 (27.50%)
occurrences (all)	0	1	12
Pruritus			
subjects affected / exposed	2 / 14 (14.29%)	0 / 8 (0.00%)	12 / 40 (30.00%)
occurrences (all)	3	0	15
Rash papular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	2 / 14 (14.29%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Nephrolithiasis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Renal colic			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Urinary tract pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Urinary tract inflammation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	3 / 40 (7.50%)
occurrences (all)	0	0	3
Hyperthyroidism			
subjects affected / exposed	3 / 14 (21.43%)	3 / 8 (37.50%)	4 / 40 (10.00%)
occurrences (all)	3	3	4
Hypophysitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1

Hypothyroidism			
subjects affected / exposed	3 / 14 (21.43%)	0 / 8 (0.00%)	5 / 40 (12.50%)
occurrences (all)	3	0	5
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 8 (12.50%)	4 / 40 (10.00%)
occurrences (all)	3	2	4
Back pain			
subjects affected / exposed	3 / 14 (21.43%)	1 / 8 (12.50%)	1 / 40 (2.50%)
occurrences (all)	3	1	1
Joint range of motion decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	1 / 14 (7.14%)	1 / 8 (12.50%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Muscle rigidity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences (all)	1	0	2
Pain in extremity			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences (all)	1	0	2
Synovial cyst			

subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 14 (7.14%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Tinea infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	2 / 40 (5.00%)
occurrences (all)	0	1	2
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	5 / 14 (35.71%)	3 / 8 (37.50%)	13 / 40 (32.50%)
occurrences (all)	5	3	15
Dehydration			
subjects affected / exposed	1 / 14 (7.14%)	1 / 8 (12.50%)	4 / 40 (10.00%)
occurrences (all)	1	1	10
Glucose tolerance impaired			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	3 / 40 (7.50%)
occurrences (all)	0	0	4
Hyperkalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Hyperglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	3
Hypoalbuminaemia			

subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	2 / 40 (5.00%)
occurrences (all)	0	1	3
Hypoglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	2
Hypokalaemia			
subjects affected / exposed	1 / 14 (7.14%)	2 / 8 (25.00%)	4 / 40 (10.00%)
occurrences (all)	1	3	5
Hypomagnesaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	2 / 40 (5.00%)
occurrences (all)	0	1	2
Hyponatraemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	2 / 40 (5.00%)
occurrences (all)	0	2	2
Hypophagia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 8 (12.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 8 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	2

Non-serious adverse events	Arm B: MK-1308 25 mg Q6W + Pembro. 200 mg Q3W	Arm C: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Cohort 2: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 40 (95.00%)	38 / 40 (95.00%)	16 / 17 (94.12%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tumour pain			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	2 / 17 (11.76%)
occurrences (all)	1	1	2
Tumour haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Hypotension			
subjects affected / exposed	2 / 40 (5.00%)	5 / 40 (12.50%)	1 / 17 (5.88%)
occurrences (all)	3	5	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	2	3	1
Catheter site pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	3 / 40 (7.50%)	2 / 40 (5.00%)	1 / 17 (5.88%)
occurrences (all)	3	2	1
Early satiety			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	9 / 40 (22.50%)	6 / 40 (15.00%)	3 / 17 (17.65%)
occurrences (all)	12	8	3
General physical health deterioration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Influenza like illness			

subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	1 / 17 (5.88%)
occurrences (all)	2	3	1
Localised oedema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Mucosal inflammation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Pyrexia			
subjects affected / exposed	4 / 40 (10.00%)	5 / 40 (12.50%)	1 / 17 (5.88%)
occurrences (all)	5	10	1
Oedema peripheral			
subjects affected / exposed	5 / 40 (12.50%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	7	1	1
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	3 / 40 (7.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	3	1	0
Drug hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Chylothorax			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dysphonia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Cough			
subjects affected / exposed	5 / 40 (12.50%)	4 / 40 (10.00%)	3 / 17 (17.65%)
occurrences (all)	5	4	3
Dyspnoea			
subjects affected / exposed	7 / 40 (17.50%)	7 / 40 (17.50%)	3 / 17 (17.65%)
occurrences (all)	9	7	3
Hypercapnia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 40 (0.00%)	4 / 40 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	4	1
Hypoxia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	4 / 40 (10.00%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	4	2	0
Pneumonitis			
subjects affected / exposed	6 / 40 (15.00%)	3 / 40 (7.50%)	0 / 17 (0.00%)
occurrences (all)	8	4	0
Productive cough			
subjects affected / exposed	5 / 40 (12.50%)	2 / 40 (5.00%)	1 / 17 (5.88%)
occurrences (all)	6	2	1
Wheezing			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	5 / 40 (12.50%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	5	2	0
Depression			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	5 / 40 (12.50%)	9 / 40 (22.50%)	1 / 17 (5.88%)
occurrences (all)	5	11	1
Ammonia increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 40 (15.00%)	11 / 40 (27.50%)	3 / 17 (17.65%)
occurrences (all)	6	15	4
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	1 / 17 (5.88%)
occurrences (all)	1	2	1
Blood corticotrophin increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	4	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	3 / 40 (7.50%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	5	4	0
C-reactive protein increased			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	1	2	1
Lipase increased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Platelet count decreased			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	1	1	1
Weight decreased			
subjects affected / exposed	4 / 40 (10.00%)	3 / 40 (7.50%)	3 / 17 (17.65%)
occurrences (all)	4	3	4
White blood cell count decreased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dental restoration failure			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	3	2	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dysaesthesia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 40 (7.50%)	5 / 40 (12.50%)	2 / 17 (11.76%)
occurrences (all)	3	5	2
Neuralgia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Seizure			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 40 (7.50%)	8 / 40 (20.00%)	2 / 17 (11.76%)
occurrences (all)	3	9	2
Eosinophilia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Thrombocytosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vision blurred			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	1	1	1
Abdominal pain upper			
subjects affected / exposed	0 / 40 (0.00%)	4 / 40 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	4	0
Aphthous ulcer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Colitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	4 / 40 (10.00%)	5 / 40 (12.50%)	3 / 17 (17.65%)
occurrences (all)	4	5	3
Dental caries			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	3 / 40 (7.50%)	9 / 40 (22.50%)	2 / 17 (11.76%)
occurrences (all)	7	15	2
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	2 / 17 (11.76%)
occurrences (all)	3	2	2

Dyspepsia			
subjects affected / exposed	2 / 40 (5.00%)	3 / 40 (7.50%)	0 / 17 (0.00%)
occurrences (all)	2	4	0
Gingival pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	5 / 40 (12.50%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	5	3	0
Obstruction gastric			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	4 / 40 (10.00%)	3 / 40 (7.50%)	5 / 17 (29.41%)
occurrences (all)	4	3	5
Small intestinal obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Dry skin			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Erythema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	2 / 17 (11.76%)
occurrences (all)	1	0	2
Rash maculo-papular			
subjects affected / exposed	3 / 40 (7.50%)	6 / 40 (15.00%)	2 / 17 (11.76%)
occurrences (all)	3	10	3
Rash			
subjects affected / exposed	14 / 40 (35.00%)	13 / 40 (32.50%)	4 / 17 (23.53%)
occurrences (all)	16	14	6
Pruritus			
subjects affected / exposed	10 / 40 (25.00%)	11 / 40 (27.50%)	6 / 17 (35.29%)
occurrences (all)	15	12	8
Rash papular			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	2 / 17 (11.76%)
occurrences (all)	1	0	3
Skin lesion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vitiligo			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	0 / 40 (0.00%)	4 / 40 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	4	0
Dysuria			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Renal colic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urinary tract inflammation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	4 / 40 (10.00%)	4 / 40 (10.00%)	1 / 17 (5.88%)
occurrences (all)	4	4	1
Hyperthyroidism			
subjects affected / exposed	3 / 40 (7.50%)	2 / 40 (5.00%)	1 / 17 (5.88%)
occurrences (all)	3	2	1
Hypophysitis			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	1	1	0

Hypothyroidism			
subjects affected / exposed	9 / 40 (22.50%)	8 / 40 (20.00%)	3 / 17 (17.65%)
occurrences (all)	9	8	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 40 (15.00%)	7 / 40 (17.50%)	2 / 17 (11.76%)
occurrences (all)	11	11	2
Back pain			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	2	2	1
Joint range of motion decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	2	2	0
Muscle rigidity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	2	2	0
Musculoskeletal pain			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	1 / 40 (2.50%)	5 / 40 (12.50%)	1 / 17 (5.88%)
occurrences (all)	1	6	1
Pain in extremity			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Synovial cyst			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	3	0
Oral candidiasis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Sinusitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	3 / 40 (7.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	5	2	0
Oral herpes			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1

Tinea infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	5 / 40 (12.50%)	5 / 40 (12.50%)	1 / 17 (5.88%)
occurrences (all)	5	7	1
Urinary tract infection			
subjects affected / exposed	3 / 40 (7.50%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	7	8	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	12 / 40 (30.00%)	8 / 40 (20.00%)	3 / 17 (17.65%)
occurrences (all)	13	10	3
Dehydration			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	2	1	1
Glucose tolerance impaired			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	3	2	0
Hyperkalaemia			
subjects affected / exposed	4 / 40 (10.00%)	5 / 40 (12.50%)	0 / 17 (0.00%)
occurrences (all)	5	7	0
Hyperglycaemia			
subjects affected / exposed	7 / 40 (17.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	8	1	0
Hyperuricaemia			
subjects affected / exposed	1 / 40 (2.50%)	3 / 40 (7.50%)	0 / 17 (0.00%)
occurrences (all)	1	3	0
Hypocalcaemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			

subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	2	2	0
Hypoglycaemia			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Hypokalaemia			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	2 / 17 (11.76%)
occurrences (all)	2	1	2
Hypomagnesaemia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	3	0	0
Hyponatraemia			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	2 / 17 (11.76%)
occurrences (all)	2	4	2
Hypophagia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Arm D: MK-1308 75 mg Q6W + Pembro. 200 mg Q3W	Arm E: MK-1308 75 mg Q3W + Pembro. 200 mg Q3W	Arm F: MK-1308 25 mg Q6W + Pembro. 400 mg Q6W Co-admin
Total subjects affected by non-serious adverse events			
subjects affected / exposed	37 / 40 (92.50%)	13 / 14 (92.86%)	102 / 111 (91.89%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	2
Tumour pain			
subjects affected / exposed	2 / 40 (5.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	2	1	0
Tumour haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	5 / 111 (4.50%)
occurrences (all)	1	0	5
Hypotension			
subjects affected / exposed	3 / 40 (7.50%)	1 / 14 (7.14%)	2 / 111 (1.80%)
occurrences (all)	4	2	2
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 40 (10.00%)	1 / 14 (7.14%)	13 / 111 (11.71%)
occurrences (all)	4	1	15
Catheter site pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences (all)	1	0	3
Early satiety			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	11 / 40 (27.50%)	4 / 14 (28.57%)	26 / 111 (23.42%)
occurrences (all)	12	5	28
General physical health deterioration			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	1	0	1
Influenza like illness			

subjects affected / exposed	2 / 40 (5.00%)	0 / 14 (0.00%)	2 / 111 (1.80%)
occurrences (all)	2	0	2
Localised oedema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 40 (2.50%)	2 / 14 (14.29%)	0 / 111 (0.00%)
occurrences (all)	1	2	0
Mucosal inflammation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	3 / 40 (7.50%)	4 / 14 (28.57%)	9 / 111 (8.11%)
occurrences (all)	3	7	12
Oedema peripheral			
subjects affected / exposed	1 / 40 (2.50%)	1 / 14 (7.14%)	8 / 111 (7.21%)
occurrences (all)	1	2	12
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Chylothorax			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	3 / 111 (2.70%)
occurrences (all)	0	1	3
Cough			
subjects affected / exposed	6 / 40 (15.00%)	0 / 14 (0.00%)	10 / 111 (9.01%)
occurrences (all)	7	0	10
Dyspnoea			
subjects affected / exposed	5 / 40 (12.50%)	2 / 14 (14.29%)	9 / 111 (8.11%)
occurrences (all)	5	2	9
Hypercapnia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences (all)	1	0	3
Hypoxia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	4 / 40 (10.00%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	5	1	1
Productive cough			
subjects affected / exposed	4 / 40 (10.00%)	2 / 14 (14.29%)	0 / 111 (0.00%)
occurrences (all)	5	2	0
Wheezing			
subjects affected / exposed	3 / 40 (7.50%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	3	0	0
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	2
Insomnia			
subjects affected / exposed	2 / 40 (5.00%)	2 / 14 (14.29%)	8 / 111 (7.21%)
occurrences (all)	3	3	8
Depression			
subjects affected / exposed	2 / 40 (5.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	2	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	5 / 40 (12.50%)	6 / 14 (42.86%)	10 / 111 (9.01%)
occurrences (all)	7	10	13
Ammonia increased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 40 (10.00%)	6 / 14 (42.86%)	6 / 111 (5.41%)
occurrences (all)	6	12	9
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 40 (0.00%)	2 / 14 (14.29%)	6 / 111 (5.41%)
occurrences (all)	0	2	6
Blood corticotrophin increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	1	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences (all)	0	0	4
Blood creatinine increased			
subjects affected / exposed	2 / 40 (5.00%)	2 / 14 (14.29%)	1 / 111 (0.90%)
occurrences (all)	4	2	1
C-reactive protein increased			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	6 / 111 (5.41%)
occurrences (all)	0	0	7
Cortisol increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 40 (7.50%)	1 / 14 (7.14%)	4 / 111 (3.60%)
occurrences (all)	3	1	4
Lipase increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences (all)	0	0	3
Lymphocyte count decreased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	0	1	1
Weight decreased			
subjects affected / exposed	7 / 40 (17.50%)	4 / 14 (28.57%)	6 / 111 (5.41%)
occurrences (all)	7	4	6
White blood cell count decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 40 (5.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	2	1	0
Dental restoration failure			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	2 / 40 (5.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	2	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	5 / 40 (12.50%)	2 / 14 (14.29%)	7 / 111 (6.31%)
occurrences (all)	7	2	7
Hypoaesthesia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	3 / 40 (7.50%)	2 / 14 (14.29%)	14 / 111 (12.61%)
occurrences (all)	3	2	15
Neuralgia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Presyncope			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Seizure			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 40 (12.50%)	2 / 14 (14.29%)	11 / 111 (9.91%)
occurrences (all)	5	3	12
Eosinophilia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences (all)	0	0	4
Neutropenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 40 (5.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	2	0	1
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	0	1	1
Vision blurred			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	3
Abdominal pain			
subjects affected / exposed	2 / 40 (5.00%)	1 / 14 (7.14%)	13 / 111 (11.71%)
occurrences (all)	2	1	13
Abdominal pain upper			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	9 / 111 (8.11%)
occurrences (all)	0	0	9
Aphthous ulcer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	1 / 40 (2.50%)	1 / 14 (7.14%)	2 / 111 (1.80%)
occurrences (all)	1	1	2
Constipation			
subjects affected / exposed	4 / 40 (10.00%)	3 / 14 (21.43%)	14 / 111 (12.61%)
occurrences (all)	4	3	17
Dental caries			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	10 / 40 (25.00%)	3 / 14 (21.43%)	27 / 111 (24.32%)
occurrences (all)	22	6	37
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	2 / 40 (5.00%)	2 / 14 (14.29%)	9 / 111 (8.11%)
occurrences (all)	2	2	9

Dyspepsia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	2 / 111 (1.80%)
occurrences (all)	1	0	2
Gingival pain			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Inguinal hernia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	10 / 40 (25.00%)	0 / 14 (0.00%)	21 / 111 (18.92%)
occurrences (all)	16	0	24
Obstruction gastric			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	6 / 40 (15.00%)	0 / 14 (0.00%)	4 / 111 (3.60%)
occurrences (all)	6	0	4
Small intestinal obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	2 / 111 (1.80%)
occurrences (all)	0	1	3
Hypertransaminasaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	2 / 40 (5.00%)	1 / 14 (7.14%)	4 / 111 (3.60%)
occurrences (all)	2	2	4
Erythema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	8 / 40 (20.00%)	1 / 14 (7.14%)	3 / 111 (2.70%)
occurrences (all)	8	6	4
Rash			
subjects affected / exposed	4 / 40 (10.00%)	6 / 14 (42.86%)	20 / 111 (18.02%)
occurrences (all)	6	7	25
Pruritus			
subjects affected / exposed	15 / 40 (37.50%)	5 / 14 (35.71%)	38 / 111 (34.23%)
occurrences (all)	20	6	42
Rash papular			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	0	1	1
Skin lesion			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	8 / 111 (7.21%)
occurrences (all)	1	0	12
Vitiligo			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	6 / 111 (5.41%)
occurrences (all)	0	1	7
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	0	1	1
Haematuria			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	0	1	1
Hydronephrosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Urinary tract inflammation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	1	0	1
Hyperthyroidism			
subjects affected / exposed	7 / 40 (17.50%)	1 / 14 (7.14%)	3 / 111 (2.70%)
occurrences (all)	7	1	3
Hypophysitis			
subjects affected / exposed	1 / 40 (2.50%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	1	1	0

Hypothyroidism			
subjects affected / exposed	8 / 40 (20.00%)	1 / 14 (7.14%)	3 / 111 (2.70%)
occurrences (all)	8	1	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 40 (10.00%)	1 / 14 (7.14%)	14 / 111 (12.61%)
occurrences (all)	4	1	17
Back pain			
subjects affected / exposed	4 / 40 (10.00%)	2 / 14 (14.29%)	9 / 111 (8.11%)
occurrences (all)	4	2	9
Joint range of motion decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	3 / 40 (7.50%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	3	0	1
Muscle rigidity			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	0	1	1
Joint swelling			
subjects affected / exposed	1 / 40 (2.50%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	1	1	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	4
Musculoskeletal pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences (all)	2	0	3
Myalgia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 14 (0.00%)	4 / 111 (3.60%)
occurrences (all)	2	0	4
Pain in extremity			
subjects affected / exposed	2 / 40 (5.00%)	1 / 14 (7.14%)	9 / 111 (8.11%)
occurrences (all)	2	2	9
Synovial cyst			

subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	1 / 111 (0.90%)
occurrences (all)	1	0	1
Oral candidiasis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	0	1	1
Pneumonia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	2 / 111 (1.80%)
occurrences (all)	1	0	2
Oral herpes			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2

Tinea infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	5 / 40 (12.50%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences (all)	6	0	4
Urinary tract infection			
subjects affected / exposed	3 / 40 (7.50%)	0 / 14 (0.00%)	7 / 111 (6.31%)
occurrences (all)	3	0	8
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	7 / 40 (17.50%)	1 / 14 (7.14%)	18 / 111 (16.22%)
occurrences (all)	8	2	19
Dehydration			
subjects affected / exposed	3 / 40 (7.50%)	1 / 14 (7.14%)	1 / 111 (0.90%)
occurrences (all)	4	2	1
Glucose tolerance impaired			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 14 (0.00%)	3 / 111 (2.70%)
occurrences (all)	1	0	3
Hyperkalaemia			
subjects affected / exposed	1 / 40 (2.50%)	3 / 14 (21.43%)	0 / 111 (0.00%)
occurrences (all)	1	4	0
Hyperglycaemia			
subjects affected / exposed	2 / 40 (5.00%)	4 / 14 (28.57%)	5 / 111 (4.50%)
occurrences (all)	2	9	5
Hyperuricaemia			
subjects affected / exposed	1 / 40 (2.50%)	2 / 14 (14.29%)	2 / 111 (1.80%)
occurrences (all)	1	2	2
Hypocalcaemia			
subjects affected / exposed	0 / 40 (0.00%)	2 / 14 (14.29%)	2 / 111 (1.80%)
occurrences (all)	0	2	2
Hypoalbuminaemia			

subjects affected / exposed	1 / 40 (2.50%)	2 / 14 (14.29%)	6 / 111 (5.41%)
occurrences (all)	1	2	6
Hypoglycaemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 14 (7.14%)	0 / 111 (0.00%)
occurrences (all)	0	3	0
Hypokalaemia			
subjects affected / exposed	5 / 40 (12.50%)	2 / 14 (14.29%)	5 / 111 (4.50%)
occurrences (all)	10	5	5
Hypomagnesaemia			
subjects affected / exposed	4 / 40 (10.00%)	2 / 14 (14.29%)	0 / 111 (0.00%)
occurrences (all)	4	3	0
Hyponatraemia			
subjects affected / exposed	2 / 40 (5.00%)	1 / 14 (7.14%)	2 / 111 (1.80%)
occurrences (all)	3	1	2
Hypophagia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 14 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	3 / 40 (7.50%)	1 / 14 (7.14%)	2 / 111 (1.80%)
occurrences (all)	5	1	2

Non-serious adverse events	Arm F Crossover: MK-1308 25mg Q6W + Pembro. 400mg Q6W Co-admin	Arm G: MK-1308 25 mg Q6W	Arm I: MK-1308A Q6W (Co-form)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 21 (80.95%)	31 / 40 (77.50%)	26 / 29 (89.66%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Tumour pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Tumour haemorrhage			
subjects affected / exposed	2 / 21 (9.52%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	6 / 21 (28.57%)	4 / 40 (10.00%)	5 / 29 (17.24%)
occurrences (all)	6	4	5
Catheter site pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Chills			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	2 / 29 (6.90%)
occurrences (all)	0	1	3
Chest pain			
subjects affected / exposed	3 / 21 (14.29%)	0 / 40 (0.00%)	2 / 29 (6.90%)
occurrences (all)	3	0	2
Early satiety			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 21 (4.76%)	6 / 40 (15.00%)	9 / 29 (31.03%)
occurrences (all)	1	6	9
General physical health deterioration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 21 (4.76%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 21 (9.52%)	2 / 40 (5.00%)	3 / 29 (10.34%)
occurrences (all)	2	3	3
Oedema peripheral			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Drug hypersensitivity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Chylothorax			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Cough			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Hypercapnia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Pneumonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	3
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 40 (2.50%)	3 / 29 (10.34%)
occurrences (all)	1	1	3
Depression			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 21 (4.76%)	1 / 40 (2.50%)	2 / 29 (6.90%)
occurrences (all)	1	1	2
Ammonia increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 21 (14.29%)	3 / 40 (7.50%)	3 / 29 (10.34%)
occurrences (all)	3	3	4
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 21 (19.05%)	3 / 40 (7.50%)	2 / 29 (6.90%)
occurrences (all)	5	3	4
Blood corticotrophin increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 21 (4.76%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences (all)	1	1	1
Blood creatinine increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
C-reactive protein increased			

subjects affected / exposed	1 / 21 (4.76%)	3 / 40 (7.50%)	0 / 29 (0.00%)
occurrences (all)	1	3	0
Cortisol increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 21 (14.29%)	4 / 40 (10.00%)	3 / 29 (10.34%)
occurrences (all)	4	4	3
Lipase increased			
subjects affected / exposed	3 / 21 (14.29%)	2 / 40 (5.00%)	0 / 29 (0.00%)
occurrences (all)	3	2	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 21 (9.52%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	2	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	2 / 21 (9.52%)	2 / 40 (5.00%)	1 / 29 (3.45%)
occurrences (all)	2	2	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Dental restoration failure			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 21 (9.52%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 21 (14.29%)	3 / 40 (7.50%)	2 / 29 (6.90%)
occurrences (all)	3	4	2
Neuralgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 21 (19.05%)	8 / 40 (20.00%)	3 / 29 (10.34%)
occurrences (all)	4	9	4
Eosinophilia			
subjects affected / exposed	2 / 21 (9.52%)	3 / 40 (7.50%)	0 / 29 (0.00%)
occurrences (all)	2	4	0
Lymphopenia			
subjects affected / exposed	3 / 21 (14.29%)	3 / 40 (7.50%)	0 / 29 (0.00%)
occurrences (all)	4	3	0
Neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	2 / 21 (9.52%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Vision blurred			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 21 (4.76%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	1	0	1
Abdominal pain			
subjects affected / exposed	1 / 21 (4.76%)	3 / 40 (7.50%)	1 / 29 (3.45%)
occurrences (all)	1	3	1
Abdominal pain upper			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Aphthous ulcer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 21 (9.52%)	4 / 40 (10.00%)	4 / 29 (13.79%)
occurrences (all)	2	4	4
Dental caries			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	4 / 21 (19.05%)	3 / 40 (7.50%)	2 / 29 (6.90%)
occurrences (all)	4	3	4
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1

Dyspepsia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 21 (0.00%)	4 / 40 (10.00%)	1 / 29 (3.45%)
occurrences (all)	0	4	1
Obstruction gastric			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 21 (4.76%)	2 / 40 (5.00%)	1 / 29 (3.45%)
occurrences (all)	1	2	1
Small intestinal obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 21 (0.00%)	3 / 40 (7.50%)	0 / 29 (0.00%)
occurrences (all)	0	3	0
Night sweats			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 21 (0.00%)	2 / 40 (5.00%)	8 / 29 (27.59%)
occurrences (all)	0	2	8
Pruritus			
subjects affected / exposed	2 / 21 (9.52%)	9 / 40 (22.50%)	11 / 29 (37.93%)
occurrences (all)	2	9	11
Rash papular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 21 (4.76%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Vitiligo			
subjects affected / exposed	2 / 21 (9.52%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Urinary tract inflammation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hypophysitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0

Hypothyroidism			
subjects affected / exposed	1 / 21 (4.76%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 21 (14.29%)	3 / 40 (7.50%)	1 / 29 (3.45%)
occurrences (all)	3	4	1
Back pain			
subjects affected / exposed	3 / 21 (14.29%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences (all)	3	1	1
Joint range of motion decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Muscle rigidity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 40 (0.00%)	2 / 29 (6.90%)
occurrences (all)	1	0	3
Musculoskeletal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 21 (9.52%)	2 / 40 (5.00%)	1 / 29 (3.45%)
occurrences (all)	3	2	1
Pain in extremity			
subjects affected / exposed	2 / 21 (9.52%)	2 / 40 (5.00%)	1 / 29 (3.45%)
occurrences (all)	2	2	1
Synovial cyst			

subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Conjunctivitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0

Tinea infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	2 / 29 (6.90%)
occurrences (all)	0	1	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 21 (9.52%)	2 / 40 (5.00%)	2 / 29 (6.90%)
occurrences (all)	2	2	3
Dehydration			
subjects affected / exposed	0 / 21 (0.00%)	1 / 40 (2.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Glucose tolerance impaired			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 21 (4.76%)	3 / 40 (7.50%)	0 / 29 (0.00%)
occurrences (all)	1	4	0
Hyperuricaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			

subjects affected / exposed	1 / 21 (4.76%)	0 / 40 (0.00%)	1 / 29 (3.45%)
occurrences (all)	1	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	3
Hyponatraemia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 40 (2.50%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Hypophagia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 40 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 40 (5.00%)	0 / 29 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Arm K: MK-1308A Q6W (Co-form)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 20 (80.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Tumour pain			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Tumour haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Vascular disorders			

Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hypertension subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hypotension subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Catheter site pain subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Chest discomfort subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Chills subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Chest pain subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Early satiety subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Fatigue subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
General physical health deterioration subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Influenza like illness			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Localised oedema			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Drug hypersensitivity			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Hypersensitivity			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Gynaecomastia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			

Chylothorax subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Dysphonia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Cough subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Dyspnoea subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hypercapnia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hypoxia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Pleural effusion subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Pneumonitis subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Productive cough subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Wheezing subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Psychiatric disorders Confusional state			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	4		
Ammonia increased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	2		
Blood corticotrophin increased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
C-reactive protein increased			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Cortisol increased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Lipase increased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	4		
Platelet count decreased			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
White blood cell count decreased			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	7		
Amylase increased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Dental restoration failure			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Animal bite			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Foot fracture			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Neuralgia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Seizure			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 20 (25.00%)		
occurrences (all)	13		
Eosinophilia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Thrombocytosis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Vision blurred			

subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Abdominal pain upper			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Aphthous ulcer			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Colitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Dental caries			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		

Dyspepsia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Gingival pain subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Haematochezia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Inguinal hernia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Nausea subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Obstruction gastric subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Small intestinal obstruction subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hepatobiliary disorders Hepatitis subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Immune-mediated hepatitis subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	4		
Pruritus			
subjects affected / exposed	8 / 20 (40.00%)		
occurrences (all)	10		
Rash papular			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Skin lesion			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Vitiligo			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	3		
Hydronephrosis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Nephrolithiasis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Renal colic			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Urinary tract pain			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Urinary tract inflammation			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Hyperthyroidism			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Hypophysitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		

Hypothyroidism			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	4		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Joint range of motion decreased			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Muscle rigidity			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Synovial cyst			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Infection			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Oral herpes			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		

Tinea infection subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3		
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
Dehydration subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Glucose tolerance impaired subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 2		
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Hypoalbuminaemia			

subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	8		
Hypoglycaemia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Hypokalaemia			
subjects affected / exposed	4 / 20 (20.00%)		
occurrences (all)	8		
Hypomagnesaemia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Hypophagia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 August 2017	AM 01: Amendment developed due to requirement by regulatory authorities around safety monitoring of Japan specific participants in the MK-1308-001 clinical trial.
04 January 2018	AM 02: The protocol was amended to add additional exploratory biomarker, safety assessments, and exclusion criteria.
20 April 2018	AM 03: The protocol was amended to explore an additional dose escalation cohort and dose confirmation arm, to modify the dose limiting toxicity (DLT) reporting period for dose confirmation, to clarify pre-treatment requirements for brain metastases, and to modify the futility analysis.
30 April 2019	AM 04: The protocol was amended to add an efficacy expansion phase in melanoma and to improve overall protocol clarity and consistency as well as to correct typographical errors identified post publishing.
07 May 2019	AM 05: The protocol was amended to add new interim analysis safety and efficacy data that supports the recommended Phase 2 dose (RP2D) used in the melanoma expansion arm.
25 December 2019	AM 06: This amendment added Process 2 material and incorporated Food and Drug Administration (FDA) feedback on Amendment 05.
18 March 2020	AM 07: This amendment added a cohort (Arm I) to evaluate a coformulated product of MK-1308 + pembrolizumab (MK-1308A).
18 November 2020	AM 08: This amendment added additional cohorts to evaluate a coformulated product of MK 1308 + pembrolizumab (MK-1308A) in the global study as well as in China-and Japan specific Arms: - Arm J - participants with programmed cell death protein 1/Ligand 1 (PD-1/L1) refractory melanoma in specific countries. - Arm K - Chinese participants who reside in China with a diagnosis of any relapsed or refractory solid tumor. Arm K is open to sites in mainland China only. - Arm L - Japanese participants who reside in Japan with a diagnosis of Stage IV non–small cell lung cancer (NSCLC). Arm L is open to sites in Japan only. Collection of pre-and on-treatment tumor biopsies from participants in Arms F, G, and J was added.
30 July 2021	AM 09: The protocol was amended to update the dose modification and toxicity management guidelines for immune-related adverse event (irAEs), to remove Arm L (Japan) from the study, to clarify pharmacokinetics (PK) collection timings, to align with the biomarker plan, and to remove Translational Oncology Research from the study.
24 January 2022	AM 10: The protocol was amended to remove Arm J from the study.
09 December 2022	AM 11: Merck Sharp & Dohme Corp. underwent an entity name and address change to Merck Sharp & Dohme LLC, Rahway, NJ, USA. This conversion resulted only in an entity name change and update to the address.

01 March 2023	AM 12: Merck Sharp & Dohme Corp. underwent an entity name and address change to Merck Sharp & Dohme LLC, Rahway, NJ, USA. This conversion resulted only in an entity name change and update to the address.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported