



Clinical trial results:

A Phase 1b Study to Assess the Safety, Tolerability and Clinical Activity of BGB-290 in Combination With Temozolomide (TMZ) in Subjects With Locally Advanced or Metastatic Solid Tumors

Summary

EudraCT number	2017-001553-14
Trial protocol	GB
Global end of trial date	04 May 2023

Results information

Result version number	v1 (current)
This version publication date	11 May 2024
First version publication date	11 May 2024

Trial information

Trial identification

Sponsor protocol code	BGB-290-103
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03150810
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BeiGene
Sponsor organisation address	1840 Gateway Drive, Third Floor, San Mateo , United States, 94404
Public contact	Clinical Trial Information Email, BeiGene USA, Inc., 01 877-828-5568, clinicaltrials@beigene.com
Scientific contact	Clinical Trial Information Email, BeiGene USA, Inc., 01 877-828-5568, clinicaltrials@beigene.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 May 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	04 May 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to determine the safety and tolerability of pamiparib, the maximum tolerated dose (MTD) or maximum administered dose (MAD) for pamiparib combined with temozolomide (TMZ), to select the recommended Phase 2 dose (RP2D) and schedule of pamiparib in combination with TMZ, and to determine the antitumor activity of pamiparib in combination with TMZ.

Protection of trial subjects:

This trial was designed and monitored in accordance with Sponsor procedures, which comply with the ethical principles of GCP as required by the major regulatory authorities, and in accordance with the Declaration of Helsinki. The IEC/IRB-approved ICF was signed and dated by the subject or the subject's legally authorized representative before his or her participation in the study. A copy of each signed ICF was provided to the subject or the subject's legally authorized representative. All signed and dated ICFs were retained in each patient's study file or in the site file. For any updated or revised ICFs, written informed consent was obtained using the IEC/IRB-approved updated/revised ICFs for continued participation in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 June 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 8
Country: Number of subjects enrolled	Spain: 43
Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	United States: 74
Worldwide total number of subjects	139
EEA total number of subjects	43

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)	78
From 65 to 84 years	60
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled in multiple study centers in Australia, Europe, and North America.

Pre-assignment

Screening details:

The study was composed of an initial screening phase (up to 28 days), a treatment phase, a safety follow-up phase (including Safety Follow-up Visit), and a survival follow-up phase.

Period 1

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

Blinding implementation details:

None (open-label)

Arms

Are arms mutually exclusive?	Yes
Arm title	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams

Arm description:

Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 40 mg once daily on Days 1 to 7 within a 28-day cycle

Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Pamiparib 60 mg administered by mouth as a capsule twice daily

Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

TMZ at various doses administered by mouth as a capsule once daily.

Arm title	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)
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Arm description:

Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 60 mg once daily on Days 1 to 7 within a 28-day cycle

Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Pamiparib 60 mg administered by mouth as a capsule twice daily

Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
TMZ at various doses administered by mouth as a capsule once daily.	
Arm title	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)
Arm description:	
Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 80 mg once daily on Days 1 to 7 within a 28-day cycle	
Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Pamiparib 60 mg administered by mouth as a capsule twice daily	
Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
TMZ at various doses administered by mouth as a capsule once daily.	
Arm title	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Arm description:	
Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 100 mg once daily on Days 1 to 7 within a 28-day cycle	
Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Pamiparib 60 mg administered by mouth as a capsule twice daily	
Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
TMZ at various doses administered by mouth as a capsule once daily.	
Arm title	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)
Arm description:	
Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 120 mg once daily on Days 1 to 7 within a 28-day cycle	
Arm type	Experimental

Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Pamiparib 60 mg administered by mouth as a capsule twice daily

Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

TMZ at various doses administered by mouth as a capsule once daily.

Arm title	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)
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Arm description:

Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 40 mg once daily on Days 1 to 14 within a 28-day cycle

Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Pamiparib 60 mg administered by mouth as a capsule twice daily

Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

TMZ at various doses administered by mouth as a capsule once daily.

Arm title	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)
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Arm description:

Pamiparib 60 mg twice daily in combination with TMZ 20 mg once daily administered continuously on Days 1 to 28 within a 28-day cycle

Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Pamiparib 60 mg administered by mouth as a capsule twice daily

Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

TMZ at various doses administered by mouth as a capsule once daily.

Arm title	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
Arm description: Pamiparib 60 mg twice daily in combination with TMZ 40 mg once daily administered continuously on Days 1 to 28 within a 28-day cycle	
Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: Pamiparib 60 mg administered by mouth as a capsule twice daily	
Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: TMZ at various doses administered by mouth as a capsule once daily.	
Arm title	Dose Expansion: Gastric Cancer

Arm description: Participants with gastric or gastroesophageal junction cancer received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: Pamiparib 60 mg administered by mouth as a capsule twice daily	
Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: TMZ 60 mg administered by mouth as a capsule once daily.	
Arm title	Dose Expansion: Ovarian Cancer

Arm description: Participants with ovarian cancer, fallopian cancer, or primary peritoneal cancer received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: Pamiparib 60 mg administered by mouth as a capsule twice daily	

Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: TMZ 60 mg administered by mouth as a capsule once daily.	
Arm title	Dose Expansion: SCLC
Arm description: Participants with Small Cell Lung Cancer (SCLC) received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: Pamiparib 60 mg administered by mouth as a capsule twice daily	
Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: TMZ 60 mg administered by mouth as a capsule once daily.	
Arm title	Dose Expansion: TNBC
Arm description: Participants with triple negative breast cancer (TNBC) received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Arm type	Experimental
Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: Pamiparib 60 mg administered by mouth as a capsule twice daily	
Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: TMZ 60 mg administered by mouth as a capsule once daily.	
Arm title	Dose Expansion: Other HRD+ Cancers
Arm description: Participants with non-small cell lung cancer (NSCLC), esophageal cancer, squamous head and neck cancer, or soft tissue sarcomas whose tumors are homologous recombination deficiency (HRD)+ received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Arm type	Experimental

Investigational medicinal product name	Pamiparib
Investigational medicinal product code	
Other name	BGB-290
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Pamiparib 60 mg administered by mouth as a capsule twice daily

Investigational medicinal product name	Temozolomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

TMZ 60 mg administered by mouth as a capsule once daily.

Number of subjects in period 1	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)
Started	4	13	9
Completed	0	0	0
Not completed	4	13	9
Consent withdrawn by subject	-	1	1
Physician decision	-	-	-
Hospice	-	-	-
Death	4	8	7
Sponsor Decision	-	2	-
Site withdrawal from study	-	1	-
Lost to follow-up	-	1	1
Participant relocated abroad	-	-	-
Transferred care to oncologist	-	-	-

Number of subjects in period 1	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)
Started	3	3	14
Completed	0	0	0
Not completed	3	3	14
Consent withdrawn by subject	1	-	-
Physician decision	-	-	1
Hospice	-	-	1
Death	2	2	10
Sponsor Decision	-	1	1
Site withdrawal from study	-	-	-
Lost to follow-up	-	-	-

Participant relocated abroad	-	-	1
Transferred care to oncologist	-	-	-

Number of subjects in period 1	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)	Dose Expansion: Gastric Cancer
	Started	14	6
Completed	0	0	0
Not completed	14	6	21
Consent withdrawn by subject	2	-	2
Physician decision	1	-	-
Hospice	-	-	-
Death	8	6	18
Sponsor Decision	-	-	1
Site withdrawal from study	-	-	-
Lost to follow-up	1	-	-
Participant relocated abroad	-	-	-
Transferred care to oncologist	2	-	-

Number of subjects in period 1	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
	Started	4	22
Completed	0	0	0
Not completed	4	22	1
Consent withdrawn by subject	-	1	-
Physician decision	-	-	-
Hospice	-	-	-
Death	3	19	1
Sponsor Decision	-	-	-
Site withdrawal from study	1	1	-
Lost to follow-up	-	1	-
Participant relocated abroad	-	-	-
Transferred care to oncologist	-	-	-

Number of subjects in period 1	Dose Expansion: Other HRD+ Cancers
Started	25
Completed	0
Not completed	25
Consent withdrawn by subject	1
Physician decision	-
Hospice	-
Death	19
Sponsor Decision	5

Site withdrawal from study	-
Lost to follow-up	-
Participant relocated abroad	-
Transferred care to oncologist	-

Baseline characteristics

Reporting groups	
Reporting group title	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 40 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 60 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 80 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 100 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 120 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 40 mg once daily on Days 1 to 14 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)
Reporting group description: Pamiparib 60 mg twice daily in combination with TMZ 20 mg once daily administered continuously on Days 1 to 28 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
Reporting group description: Pamiparib 60 mg twice daily in combination with TMZ 40 mg once daily administered continuously on Days 1 to 28 within a 28-day cycle	
Reporting group title	Dose Expansion: Gastric Cancer
Reporting group description: Participants with gastric or gastroesophageal junction cancer received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Reporting group title	Dose Expansion: Ovarian Cancer
Reporting group description: Participants with ovarian cancer, fallopian cancer, or primary peritoneal cancer received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Reporting group title	Dose Expansion: SCLC
Reporting group description: Participants with Small Cell Lung Cancer (SCLC) received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Reporting group title	Dose Expansion: TNBC
Reporting group description: Participants with triple negative breast cancer (TNBC) received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Reporting group title	Dose Expansion: Other HRD+ Cancers

Reporting group description:

Participants with non-small cell lung cancer (NSCLC), esophageal cancer, squamous head and neck cancer, or soft tissue sarcomas whose tumors are homologous recombination deficiency (HRD)+ received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle

Reporting group values	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)
Number of subjects	4	13	9
Age categorical Units: Subjects			
Adults (18-64 years)	2	8	0
From 65-84 years	2	5	8
85 years and over	0	0	1
Age continuous Units: years			
arithmetic mean	63.5	58.0	72.3
standard deviation	± 6.19	± 10.52	± 6.22
Gender categorical Units: Subjects			
Female	3	7	5
Male	1	6	4
Race (NIH/OMB) Units: Subjects			
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	4	10	9
Unknown or Not Reported	0	2	0

Reporting group values	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)
Number of subjects	3	3	14
Age categorical Units: Subjects			
Adults (18-64 years)	2	1	5
From 65-84 years	1	2	9
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	60.3	65.7	66.7
standard deviation	± 10.69	± 13.80	± 10.21
Gender categorical Units: Subjects			
Female	2	1	6
Male	1	2	8
Race (NIH/OMB) Units: Subjects			
Asian	0	0	1

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	2	3
White	2	1	7
Unknown or Not Reported	0	0	3

Reporting group values	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)	Dose Expansion: Gastric Cancer
Number of subjects	14	6	21
Age categorical Units: Subjects			
Adults (18-64 years)	5	3	13
From 65-84 years	9	3	8
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	66.9	66.7	58.8
standard deviation	± 9.96	± 8.31	± 14.68
Gender categorical Units: Subjects			
Female	7	2	8
Male	7	4	13
Race (NIH/OMB) Units: Subjects			
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	1	1	1
White	8	5	18
Unknown or Not Reported	5	0	1

Reporting group values	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
Number of subjects	4	22	1
Age categorical Units: Subjects			
Adults (18-64 years)	4	13	1
From 65-84 years	0	9	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	59.3	61.9	31.0
standard deviation	± 2.22	± 8.33	± 9999
Gender categorical Units: Subjects			
Female	4	8	1
Male	0	14	0
Race (NIH/OMB) Units: Subjects			
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0

White	2	18	1
Unknown or Not Reported	1	4	0

Reporting group values	Dose Expansion: Other HRD+ Cancers	Total	
Number of subjects	25	139	
Age categorical Units: Subjects			
Adults (18-64 years)	21	78	
From 65-84 years	4	60	
85 years and over	0	1	
Age continuous Units: years			
arithmetic mean	58.1		
standard deviation	± 8.28	-	
Gender categorical Units: Subjects			
Female	10	64	
Male	15	75	
Race (NIH/OMB) Units: Subjects			
Asian	0	2	
Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	0	10	
White	20	105	
Unknown or Not Reported	5	21	

End points

End points reporting groups

Reporting group title	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 40 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 60 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 80 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 100 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 120 mg once daily on Days 1 to 7 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)
Reporting group description: Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 40 mg once daily on Days 1 to 14 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)
Reporting group description: Pamiparib 60 mg twice daily in combination with TMZ 20 mg once daily administered continuously on Days 1 to 28 within a 28-day cycle	
Reporting group title	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
Reporting group description: Pamiparib 60 mg twice daily in combination with TMZ 40 mg once daily administered continuously on Days 1 to 28 within a 28-day cycle	
Reporting group title	Dose Expansion: Gastric Cancer
Reporting group description: Participants with gastric or gastroesophageal junction cancer received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Reporting group title	Dose Expansion: Ovarian Cancer
Reporting group description: Participants with ovarian cancer, fallopian cancer, or primary peritoneal cancer received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Reporting group title	Dose Expansion: SCLC
Reporting group description: Participants with Small Cell Lung Cancer (SCLC) received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Reporting group title	Dose Expansion: TNBC
Reporting group description: Participants with triple negative breast cancer (TNBC) received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle	
Reporting group title	Dose Expansion: Other HRD+ Cancers

Reporting group description:

Participants with non-small cell lung cancer (NSCLC), esophageal cancer, squamous head and neck cancer, or soft tissue sarcomas whose tumors are homologous recombination deficiency (HRD)+ received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle

Subject analysis set title	Pamiparib 60 mg BID
Subject analysis set type	Full analysis

Subject analysis set description:

Pharmacokinetic (PK) Analysis Set included all participants who received any dose of pamiparib and contributed at least one plasma concentration.

Primary: Dose Escalation: Number of Participants With Dose Limiting Toxicities (DLTs)

End point title	Dose Escalation: Number of Participants With Dose Limiting Toxicities (DLTs) ^{[1][2]}
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End point description:

A DLT is defined as one of the following toxicities occurring during the DLT assessment window:

Grade ≥ 3 non-hematologic, non-hepatic major organ adverse event (AE) Grade 4 neutropenia lasting > 7 days Grade ≥ 3 febrile neutropenia Grade 3 thrombocytopenia with clinically significant bleeding Grade 4 thrombocytopenia lasting > 3 days and requiring transfusion, or any decreased platelet count $< 15,000/\text{mm}^3/ < 15.0 \times 10^9/\text{L}$ Grade ≥ 4 anemia Grade ≥ 3 total bilirubin or hepatic transaminases (ALT or AST)

The dose-escalation safety analysis set comprised all dose-escalation phase participants who received pamiparib and/or TMZ.

End point type	Primary
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End point timeframe:

From first dose of study drug(s) to 28 days post-dose (up to approximately 1 year and 6 months)

Notes:

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

Justification: No statistical analysis available for descriptive data

[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: No statistical analysis available for descriptive data

End point values	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	13	9	3
Units: Number of Participants	0	0	0	2

End point values	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	14	14	
Units: Number of Participants	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Experiencing Adverse Events (AEs)

End point title	Number of Participants Experiencing Adverse Events (AEs) ^[3]
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End point description:

Number of participants with treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs), including laboratory values, vital signs, physical examination findings, and electrocardiogram results, graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), v4.03

The Safety Analysis Set included all participants who received any dose of pamiparib and/or TMZ.

End point type	Primary
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End point timeframe:

From the first dose of study drug(s) to 30 days after the last dose; up to approximately 5 years and 10 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 analysis available for descriptive data

End point values	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	13	9	3
Units: Number of Participants				
Participants With At Least 1 TEAE	4	13	9	3
Participants with Serious TEAEs	1	4	1	2

End point values	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	14	14	6
Units: Number of Participants				
Participants With At Least 1 TEAE	3	14	14	6
Participants with Serious TEAEs	2	5	5	0

End point values	Dose Expansion: Gastric Cancer	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	4	22	1
Units: Number of Participants				
Participants With At Least 1 TEAE	20	4	22	1
Participants with Serious TEAEs	9	3	9	0

End point values	Dose Expansion: Other HRD+ Cancers			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Number of Participants				
Participants With At Least 1 TEAE	24			
Participants with Serious TEAEs	9			

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR) ^[4]
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End point description:

ORR is defined as the percentage of participants who have a best overall response (BOR) of complete response (CR) or partial response (PR) based on investigator assessment using Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, where BOR is defined as the best response recorded from the first postbaseline tumor assessment until data cutoff date, disease progression or start of new anticancer treatment.

The Efficacy Analysis Set included all participants who were in the safety analysis set, had measurable disease at baseline and had at least one postbaseline tumor assessment unless discontinued treatment due to clinical progression or death prior to tumor assessment.

End point type	Primary
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End point timeframe:

Up to approximately 5 years and 10 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 analysis available for descriptive data

End point values	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	2
Units: Percentage of Participants				
number (confidence interval 90%)	0.0 (0.0 to 63.2)	16.7 (3.0 to 43.8)	25.0 (4.6 to 60.0)	0.0 (0.0 to 77.6)

End point values	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	14	13	4
Units: Percentage of Participants				
number (confidence interval 90%)	0.0 (0.0 to 77.6)	21.4 (6.1 to 46.6)	0.0 (0.0 to 20.6)	25.0 (1.3 to 75.1)

End point values	Dose Expansion: Gastric Cancer	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	4	20	1
Units: Percentage of Participants				
number (confidence interval 90%)	0.0 (0.0 to 14.6)	50.0 (9.8 to 90.2)	15.0 (4.2 to 34.4)	100.0 (5.0 to 100.0)

End point values	Dose Expansion: Other HRD+ Cancers			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Percentage of Participants				
number (confidence interval 90%)	8.0 (1.4 to 23.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (C_{max}) of Pamiparib

End point title	Maximum Observed Plasma Concentration (Cmax) of Pamiparib
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End point description:

Pharmacokinetic (PK) Analysis Set included all participants who received any dose of pamiparib and contributed at least one plasma concentration.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 15 of 28-day cycle

End point values	Pamiparib 60 mg BID			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	1945.31 (\pm 25)			

Statistical analyses

No statistical analyses for this end point

Secondary: Steady State Maximum Observed Plasma Concentration (Cmax) of Pamiparib

End point title	Steady State Maximum Observed Plasma Concentration (Cmax) of Pamiparib
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End point description:

Pharmacokinetic (PK) Analysis Set included all participants who received any dose of pamiparib and contributed at least one plasma concentration.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 15 of 28-day cycle

End point values	Pamiparib 60 mg BID			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	3796.08 (\pm 33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Steady State Lowest Concentration Reached Before the Next Dose Administered (Ctough) of Pamiparib

End point title	Steady State Lowest Concentration Reached Before the Next Dose Administered (Ctough) of Pamiparib
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End point description:

Pharmacokinetic (PK) Analysis Set included all participants who received any dose of pamiparib and contributed at least one plasma concentration.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 15 of 28-day cycle

End point values	Pamiparib 60 mg BID			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	2335.6 (\pm 76)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Cmax (Tmax) of Pamiparib

End point title	Time to Reach Cmax (Tmax) of Pamiparib
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End point description:

Pharmacokinetic (PK) Analysis Set included all participants who received any dose of pamiparib and contributed at least one plasma concentration.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 15 of 28-day cycle

End point values	Pamiparib 60 mg BID			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: Hours				
median (full range (min-max))	1.83 (0.83 to 2.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Elimination Half-life (t_{1/2}) of Pamiparib

End point title | Terminal Elimination Half-life (t_{1/2}) of Pamiparib

End point description:

Pharmacokinetic (PK) Analysis Set included all participants who received any dose of pamiparib and contributed at least one plasma concentration.

End point type | Secondary

End point timeframe:

Cycle 1 Day 15 of 28-day cycle

End point values	Pamiparib 60 mg BID			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: Hours				
geometric mean (full range (min-max))	11.825 (5.94 to 33.58)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Clearance (CL/F) of Pamiparib

End point title | Apparent Clearance (CL/F) of Pamiparib

End point description:

Pharmacokinetic (PK) Analysis Set included all participants who received any dose of pamiparib and contributed at least one plasma concentration.

End point type | Secondary

End point timeframe:

Cycle 1 Day 15 of 28-day cycle

End point values	Pamiparib 60 mg BID			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: L/h				
geometric mean (geometric coefficient of variation)	38.14 (\pm 15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Volume of Distribution During Terminal Phase (Vz/F) of Pamiparib

End point title	Apparent Volume of Distribution During Terminal Phase (Vz/F) of Pamiparib			
End point description:	Pharmacokinetic (PK) Analysis Set included all participants who received any dose of pamiparib and contributed at least one plasma concentration.			
End point type	Secondary			
End point timeframe:	Cycle 1 Day 15 of 28-day cycle			

End point values	Pamiparib 60 mg BID			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: Liters				
geometric mean (geometric coefficient of variation)	38.14 (\pm 15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR)

End point title	Disease Control Rate (DCR)			
End point description:	DCR is defined as the percentage of participants with BOR of CR, PR, or stable disease (SD) based on investigator assessment using RECIST v1.1; The Efficacy Analysis Set included all participants who were in the safety analysis set, had measurable disease at baseline and had at least one postbaseline tumor assessment unless discontinued treatment due to clinical progression or death prior to tumor assessment.			
End point type	Secondary			
End point timeframe:	Up to approximately 5 years and 10 months			

End point values	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	2
Units: Percentage of Participants				
number (confidence interval 90%)	33.3 (1.7 to 86.5)	91.7 (66.1 to 99.6)	75.0 (40.0 to 95.4)	100.0 (22.4 to 100.0)

End point values	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	14	13	4
Units: Percentage of Participants				
number (confidence interval 90%)	50.0 (2.5 to 97.5)	42.9 (20.6 to 67.5)	53.8 (28.7 to 77.6)	75.0 (24.9 to 98.7)

End point values	Dose Expansion: Gastric Cancer	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	4	20	1
Units: Percentage of Participants				
number (confidence interval 90%)	42.1 (23.0 to 63.2)	75.0 (24.9 to 98.7)	75.0 (54.4 to 89.6)	100.0 (5.0 to 100.0)

End point values	Dose Expansion: Other HRD+ Cancers			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Percentage of Participants				
number (confidence interval 90%)	52.0 (34.1 to 69.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)
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End point description:

DOR is defined as the time from the date of the earliest documented CR or PR (that is subsequently confirmed) to disease progression or death due to any cause, whichever occurs earlier, based on investigator assessment using RECIST v1.1. Only responders will be included in the assessment.

The Efficacy Analysis Set included all participants who were in the safety analysis set, had measurable disease at baseline and had at least one postbaseline tumor assessment unless discontinued treatment due to clinical progression or death prior to tumor assessment.

End point type	Secondary
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End point timeframe:

Up to approximately 5 years and 10 months

End point values	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[5]	2 ^[6]	2 ^[7]	0 ^[8]
Units: months				
median (confidence interval 90%)	(to)	13.0 (0000 to 9999)	6.4 (5.5 to 9999)	(to)

Notes:

[5] - NA = Not estimable due to insufficient number of participants with events

[6] - 0000/9999- Not estimable due to insufficient number of participants with events

[7] - 9999- Not estimable due to insufficient number of participants with events

[8] - Not estimable due to insufficient number of participants with events

End point values	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[9]	3 ^[10]	0 ^[11]	1 ^[12]
Units: months				
median (confidence interval 90%)	(to)	9.2 (7.7 to 9999)	(to)	3.7 (0000 to 9999)

Notes:

[9] - Not estimable due to insufficient number of participants with events

[10] - 9999- Not estimable due to insufficient number of participants with events

[11] - Not estimable due to insufficient number of participants with events

[12] - 0000/9999- Not estimable due to insufficient number of participants with events

End point values	Dose Expansion: Gastric Cancer	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[13]	2 ^[14]	3 ^[15]	1 ^[16]
Units: months				
median (confidence interval 90%)	(to)	5.4 (4.9 to 9999)	3.8 (3.2 to 9999)	11.0 (0000 to 9999)

Notes:

[13] - Not estimable due to insufficient number of participants with events

[14] - 9999- Not estimable due to insufficient number of participants with events

[15] - 9999- Not estimable due to insufficient number of participants with events

[16] - 0000/9999- Not estimable due to insufficient number of participants with events

End point values	Dose Expansion: Other HRD+ Cancers			
Subject group type	Reporting group			
Number of subjects analysed	2 ^[17]			
Units: months				
median (confidence interval 90%)	9999 (7.4 to 9999)			

Notes:

[17] - 9999- Not estimable due to insufficient number of participants with events

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)
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End point description:

PFS is defined as the time (months) from the date of the first dose of combination treatment to disease progression or death due to any cause, whichever occurs first, based on investigator assessment using RECIST v1.1

End point type	Secondary
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End point timeframe:

Up to approximately 5 years and 10 months

End point values	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[18]	12	8	2
Units: Months				
median (confidence interval 90%)	2.0 (1.2 to 9999)	5.6 (2.7 to 22.0)	5.3 (1.8 to 7.5)	9999 (4.5 to 9999)

Notes:

[18] - 9999 = Not estimable due to insufficient number of participants with events

End point values	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	14	13	4
Units: Months				
median (confidence interval 90%)	9999 (1.8 to 9999)	2.8 (1.7 to 3.7)	3.1 (1.7 to 3.9)	3.5 (1.1 to 9999)

End point values	Dose Expansion: Gastric Cancer	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	4	20	1 ^[19]
Units: Months				
median (confidence interval 90%)	1.9 (1.7 to 3.3)	6.4 (2.6 to 9999)	3.5 (2.3 to 4.1)	14.8 (0000 to 9999)

Notes:

[19] - 0000/9999 = Not estimable due to insufficient number of participants with events

End point values	Dose Expansion: Other HRD+ Cancers			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Months				
median (confidence interval 90%)	2.6 (1.9 to 3.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
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End point description:

OS is defined as the time from the date of the first dose of combination treatment to death due to any cause;

The Safety Analysis Set included all participants who received any dose of pamiparib and/or TMZ.

End point type	Secondary
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End point timeframe:

Up to approximately 5 years and 10 months

End point values	Dose Escalation: Pamiparib + temozolomide (TMZ) 40 milligrams	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[20]	13	9	3
Units: Months				
median (confidence interval 90%)	7.6 (2.2 to 9999)	14.8 (8.4 to 9999)	12.7 (9.4 to 9999)	12.4 (4.5 to 9999)

Notes:

[20] - 9999 = Not estimable due to insufficient number of participants with events

End point values	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	14	14	6
Units: Months				
median (confidence interval 90%)	12.3 (4.2 to 9999)	6.3 (3.4 to 31.8)	13.9 (8.0 to 9999)	8.2 (1.1 to 12.7)

End point values	Dose Expansion: Gastric Cancer	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	4	22	1
Units: Months				
median (confidence interval 90%)	6.6 (3.8 to 9.9)	21.2 (11.1 to 9999)	7.7 (4.1 to 13.1)	19.4 (0000 to 9999)

End point values	Dose Expansion: Other HRD+ Cancers			
Subject group type	Reporting group			
Number of subjects analysed	25 ^[21]			
Units: Months				
median (confidence interval 90%)	9.8 (7.6 to 11.7)			

Notes:

[21] - 0000/9999 = Not estimable due to insufficient number of participants with events

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality and adverse events (AEs): From the first dose of study drug(s) to 30 days after the last dose; up to approximately 5 years and 10 months

Adverse event reporting additional description:

All-cause mortality is reported for all randomized participants. Serious and other adverse events include all randomized participants who received ≥ 1 dose of any study treatment

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21
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Reporting groups

Reporting group title	Dose Escalation: Pamiparib + Temozolomide (TMZ) 40 mg (Days 1-
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Reporting group description:

Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 40 mg once daily on Days 1 to 7 within a 28-day cycle

Reporting group title	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)
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Reporting group description:

Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 60 mg once daily on Days 1 to 7 within a 28-day cycle

Reporting group title	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)
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Reporting group description:

Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 80 mg once daily on Days 1 to 7 within a 28-day cycle

Reporting group title	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)
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Reporting group description:

Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 100 mg once daily on Days 1 to 7 within a 28-day cycle

Reporting group title	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)
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Reporting group description:

Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 120 mg once daily on Days 1 to 7 within a 28-day cycle

Reporting group title	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)
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Reporting group description:

Pamiparib 60 mg twice daily on Days 1 to 28 in combination with pulse dosing of TMZ 40 mg once daily on Days 1 to 14 within a 28-day cycle

Reporting group title	Dose Expansion: Other HRD+ Cancers
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Reporting group description:

Participants with non-small cell lung cancer (NSCLC), esophageal cancer, squamous head and neck cancer, or soft tissue sarcomas whose tumors are homologous recombination deficiency (HRD)+ received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle

Reporting group title	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)
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Reporting group description:

Pamiparib 60 mg twice daily in combination with TMZ 40 mg once daily administered continuously on Days 1 to 28 within a 28-day cycle

Reporting group title	Dose Expansion: Gastric Cancer
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Reporting group description:

Participants with gastric or gastroesophageal junction cancer received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle

Reporting group title	Dose Expansion: Ovarian Cancer
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Reporting group description:

Participants with ovarian cancer, fallopian cancer, or primary peritoneal cancer received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle

Reporting group title	Dose Expansion: SCLC
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Reporting group description:

Participants with Small Cell Lung Cancer (SCLC) received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle

Reporting group title	Dose Expansion: TNBC
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Reporting group description:

Participants with triple negative breast cancer (TNBC) received TMZ 60 mg administered on Days 1 to 7 in combination with pamiparib 60 mg twice daily on Days 1 to 28 of each cycle

Reporting group title	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)
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Reporting group description:

Pamiparib 60 mg twice daily in combination with TMZ 20 mg once daily administered continuously on Days 1 to 28 within a 28-day cycle

Serious adverse events	Dose Escalation: Pamiparib + Temozolomide (TMZ) 40 mg (Days 1-	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	4 / 13 (30.77%)	1 / 9 (11.11%)
number of deaths (all causes)	4	8	7
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Superior vena cava syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Stoma site haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Right-to-left cardiac shunt			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ataxia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Precerebral artery embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 13 (15.38%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	0 / 9 (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
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	5 / 14 (35.71%)
number of deaths (all causes)	2	2	10
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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			
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 14 (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
Pneumothorax			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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			
Stoma site haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
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 compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (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
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Right-to-left cardiac shunt			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Precerebral artery embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
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 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 14 (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			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (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
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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			
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Appendicitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
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			

Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
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	Dose Expansion: Other HRD+ Cancers	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)	Dose Expansion: Gastric Cancer
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 25 (36.00%)	0 / 6 (0.00%)	9 / 21 (42.86%)
number of deaths (all causes)	19	6	18
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Superior vena cava syndrome			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			

subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Alanine aminotransferase increased subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Stoma site haemorrhage subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Right-to-left cardiac shunt subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ataxia subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Precerebral artery embolism			

subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oesophagitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia			

subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Appendicitis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	9 / 22 (40.91%)	0 / 1 (0.00%)
number of deaths (all causes)	3	19	1
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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			
Superior vena cava syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (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
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (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
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (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
Alanine aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (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
Injury, poisoning and procedural complications			
Stoma site haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 compression fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Right-to-left cardiac shunt			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ataxia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Precerebral artery embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (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
Neutropenia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (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
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (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
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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			
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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			
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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			
COVID-19			

subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			

subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (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
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	2 / 22 (9.09%)	0 / 1 (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
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (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 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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			
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
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	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 14 (35.71%)		
number of deaths (all causes)	8		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Superior vena cava syndrome			
subjects affected / exposed	0 / 14 (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 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			

subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Stoma site haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Spinal compression fracture subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Right-to-left cardiac shunt subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Ataxia subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Precerebral artery embolism subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral sensory neuropathy subjects affected / exposed	0 / 14 (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 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysphagia			

subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric perforation			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal obstruction			
subjects affected / exposed	0 / 14 (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 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophagitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute kidney injury			

subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocarditis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary sepsis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Groin abscess			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Abdominal abscess			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infectious pleural effusion			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			

Hypoglycaemia			
subjects affected / exposed	0 / 14 (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: 3 %

Non-serious adverse events	Dose Escalation: Pamiparib + Temozolomide (TMZ) 40 mg (Days 1-	Dose Escalation: Pamiparib + TMZ 60 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 80 mg (Days 1-7)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	13 / 13 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Malignant ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vascular disorders			
Capillary fragility			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hot flush			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral venous disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 4 (25.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Early satiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	9 / 13 (69.23%)	5 / 9 (55.56%)
occurrences (all)	2	10	5
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 1	0 / 9 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	1 / 9 (11.11%) 1
Localised oedema subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 1	0 / 9 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 13 (15.38%) 2	2 / 9 (22.22%) 2
Sluggishness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 1	0 / 9 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	1 / 13 (7.69%) 2	1 / 9 (11.11%) 1
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 1	0 / 9 (0.00%) 0
Vascular device occlusion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 3	0 / 9 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Reproductive system and breast disorders Nipple pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Heavy menstrual bleeding			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 4 (50.00%)	2 / 13 (15.38%)	1 / 9 (11.11%)
occurrences (all)	2	2	2
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 13 (15.38%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	2 / 13 (15.38%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	3 / 13 (23.08%)	1 / 9 (11.11%)
occurrences (all)	1	3	1
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nasal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Rhinitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	3 / 13 (23.08%)	1 / 9 (11.11%)
occurrences (all)	0	3	1
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 13 (15.38%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	2 / 9 (22.22%)
occurrences (all)	0	1	2
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 13 (15.38%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood calcium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 13 (15.38%)	2 / 9 (22.22%)
occurrences (all)	0	2	2
Platelet count decreased			

subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 13 (0.00%) 0	3 / 9 (33.33%) 5
Weight decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	2 / 9 (22.22%) 2
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 1	3 / 9 (33.33%) 3
Injury, poisoning and procedural complications			
Compression fracture subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Foot fracture subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	1 / 9 (11.11%) 1
Fibula fracture subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 3	1 / 9 (11.11%) 1
Contusion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 13 (15.38%) 2	0 / 9 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 1	0 / 9 (0.00%) 0
Radius fracture subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	1 / 9 (11.11%) 1
Cardiac disorders			

Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aortic valve disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Areflexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Cognitive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	1 / 13 (7.69%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Dizziness postural			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Dysaesthesia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	4 / 13 (30.77%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Dysgeusia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 13 (7.69%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Dysarthria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Multiple sclerosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Mental impairment			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	8 / 13 (61.54%)	5 / 9 (55.56%)
occurrences (all)	0	11	8
Lymphadenopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 4 (25.00%)	5 / 13 (38.46%)	4 / 9 (44.44%)
occurrences (all)	3	10	5
Neutropenia			
subjects affected / exposed	1 / 4 (25.00%)	4 / 13 (30.77%)	3 / 9 (33.33%)
occurrences (all)	1	8	5
Thrombocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Ocular hyperaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Photophobia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 13 (15.38%)	2 / 9 (22.22%)
occurrences (all)	0	2	2
Abdominal distension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	3 / 13 (23.08%)	3 / 9 (33.33%)
occurrences (all)	0	5	4
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Flatulence			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	3 / 4 (75.00%)	9 / 13 (69.23%)	5 / 9 (55.56%)
occurrences (all)	3	12	5
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Saliva altered			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Small intestinal perforation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Tongue pigmentation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 2	5 / 13 (38.46%) 5	1 / 9 (11.11%) 1
Hepatobiliary disorders			
Gallbladder obstruction			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Hepatomegaly			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Hypertransaminaemia			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 2	0 / 9 (0.00%) 0
Hyperbilirubinaemia			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Dry skin			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Ecchymosis			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Hyperhidrosis			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	1 / 9 (11.11%) 1
Nail discolouration			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 1	0 / 9 (0.00%) 0
Onychoclasia			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Nail disorder			

subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Xanthoma			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Renal colic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Nocturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urethral stenosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	4 / 13 (30.77%)	0 / 9 (0.00%)
occurrences (all)	1	4	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	3 / 13 (23.08%)	1 / 9 (11.11%)
occurrences (all)	0	4	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Muscular weakness			

subjects affected / exposed	1 / 4 (25.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Muscle tightness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	2 / 13 (15.38%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Osteopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Groin abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Groin infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Influenza subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Infected bite subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 13 (7.69%) 1	0 / 9 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Onychomycosis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Lower respiratory tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Oropharyngeal candidiasis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0
Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 13 (0.00%) 0	0 / 9 (0.00%) 0

Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	6 / 13 (46.15%)	2 / 9 (22.22%)
occurrences (all)	1	6	2
Dehydration			
subjects affected / exposed	1 / 4 (25.00%)	3 / 13 (23.08%)	1 / 9 (11.11%)
occurrences (all)	1	3	1
Gout			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 13 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	2
Vitamin D deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 13 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 4 (0.00%)	1 / 13 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Dose Escalation: Pamiparib + TMZ 100 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 120 mg (Days 1-7)	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-14)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	14 / 14 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Malignant ascites			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Infected neoplasm subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Cancer pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Vascular disorders Capillary fragility subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Haematoma subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Hypertension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	2 / 14 (14.29%) 2
Hypotension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Peripheral venous disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 14 (0.00%) 0
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Axillary pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	10 / 14 (71.43%)
occurrences (all)	2	1	10
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	3 / 14 (21.43%)
occurrences (all)	1	0	3
Sluggishness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	4 / 14 (28.57%)
occurrences (all)	0	1	5
Peripheral swelling			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Vascular device occlusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 14 (0.00%) 0
Reproductive system and breast disorders Nipple pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 14 (0.00%) 0
Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Aphonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	3 / 14 (21.43%) 3
Dysphonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Haemoptysis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Epistaxis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Dyspnoea exertional			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 14 (14.29%)
occurrences (all)	4	0	2
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Wheezing subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	2 / 14 (14.29%) 2
Hallucination subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Depression subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Investigations Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	3 / 14 (21.43%) 3
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	3 / 14 (21.43%) 3
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	3 / 14 (21.43%) 3
Blood calcium decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Weight decreased			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Foot fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Fall			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 2
Contusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 14 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Radius fracture subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 14 (0.00%) 0
Cardiac disorders Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 14 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Aortic valve disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 14 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Nervous system disorders Balance disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Areflexia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Aphasia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	3 / 14 (21.43%)
occurrences (all)	1	0	3
Dizziness postural			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	3
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Multiple sclerosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mental impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Paraparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	3 / 3 (100.00%)	10 / 14 (71.43%)
occurrences (all)	8	4	15

Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 14 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 6	3 / 3 (100.00%) 9	7 / 14 (50.00%) 15
Neutropenia subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 8	3 / 3 (100.00%) 4	5 / 14 (35.71%) 16
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Ear and labyrinth disorders			
Deafness unilateral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Vertigo subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Eye disorders			
Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Glaucoma subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Cataract subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Iridocyclitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Anorectal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	4 / 14 (28.57%)
occurrences (all)	1	1	4
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Haemorrhoidal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hypoaesthesia oral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	2 / 3 (66.67%) 2	5 / 14 (35.71%) 6
Oral pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Oesophagitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Oesophageal pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Odynophagia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Regurgitation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Upper gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Saliva altered subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0

Salivary hypersecretion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Small intestinal obstruction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Small intestinal perforation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Tongue pigmentation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Vomiting subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	2 / 3 (66.67%) 2	4 / 14 (28.57%) 10
Hepatobiliary disorders Gallbladder obstruction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hepatomegaly subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hypertransaminaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Dry skin			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onychoclasia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Nail disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Xanthoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Urethral stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	2 / 14 (14.29%)
occurrences (all)	1	2	2
Back pain			

subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	3 / 14 (21.43%)
occurrences (all)	1	1	3
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Muscle tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Osteopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Groin abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Groin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infected bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 14 (0.00%)
occurrences (all)	0	1	0

Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	4 / 14 (28.57%)
occurrences (all)	1	0	4
Dehydration			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	5 / 14 (35.71%) 5
Gout			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hypercalcaemia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hyperglycaemia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	2 / 14 (14.29%) 2
Hyperkalaemia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hypernatraemia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hypoalbuminaemia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hyponatraemia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	2 / 14 (14.29%) 2
Hypomagnesaemia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 14 (0.00%) 0
Hypokalaemia			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	1 / 3 (33.33%) 2	4 / 14 (28.57%) 6
Hypocalcaemia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 1
Hypophosphataemia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 14 (7.14%) 3
Vitamin D deficiency			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vitamin B12 deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose Expansion: Other HRD+ Cancers	Dose Escalation: Pamiparib + TMZ 40 mg (Days 1-28)	Dose Expansion: Gastric Cancer
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 25 (96.00%)	6 / 6 (100.00%)	20 / 21 (95.24%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Malignant ascites			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Infected neoplasm			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Vascular disorders			
Capillary fragility			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Peripheral venous disease subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 7	0 / 6 (0.00%) 0	1 / 21 (4.76%) 2
Axillary pain subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Early satiety subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	7 / 25 (28.00%) 9	2 / 6 (33.33%) 2	12 / 21 (57.14%) 13
Gait disturbance subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Non-cardiac chest pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Malaise			

subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Localised oedema subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 6 (16.67%) 1	0 / 21 (0.00%) 0
Sluggishness subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	1 / 21 (4.76%) 2
Peripheral swelling subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Vascular device occlusion subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Reproductive system and breast disorders Nipple pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Respiratory, thoracic and mediastinal disorders			

Aphonia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	4 / 25 (16.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	6	0	1
Dysphonia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	3 / 25 (12.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	3	1	1
Hiccups			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Increased bronchial secretion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Productive cough			
subjects affected / exposed	2 / 25 (8.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Pleural effusion			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasal inflammation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 25 (8.00%)	2 / 6 (33.33%)	1 / 21 (4.76%)
occurrences (all)	2	2	1
Hallucination			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	2 / 6 (33.33%) 2	1 / 21 (4.76%) 1
Investigations			
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	2 / 6 (33.33%) 2	3 / 21 (14.29%) 3
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	2 / 21 (9.52%) 2
Blood bilirubin increased subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	1 / 6 (16.67%) 1	2 / 21 (9.52%) 4
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 5	1 / 6 (16.67%) 1	2 / 21 (9.52%) 2
Blood calcium decreased subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Lymphocyte count decreased subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Neutrophil count decreased subjects affected / exposed occurrences (all)	8 / 25 (32.00%) 15	2 / 6 (33.33%) 2	4 / 21 (19.05%) 5
Platelet count decreased subjects affected / exposed occurrences (all)	8 / 25 (32.00%) 8	2 / 6 (33.33%) 2	5 / 21 (23.81%) 5
Weight decreased			

subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 6 (0.00%) 0	2 / 21 (9.52%) 2
White blood cell count decreased subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	2 / 6 (33.33%) 2	1 / 21 (4.76%) 1
Injury, poisoning and procedural complications			
Compression fracture subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Foot fracture subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Fibula fracture subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Radius fracture subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Cardiac disorders			
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Palpitations			

subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Aortic valve disease subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Nervous system disorders			
Balance disorder subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Areflexia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Aphasia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Cognitive disorder subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Depressed level of consciousness subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	2 / 21 (9.52%) 2
Dizziness postural subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Dysaesthesia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0

Dysgeusia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Dysarthria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Multiple sclerosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Mental impairment			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Paraparesis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Parosmia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2

Taste disorder subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	2 / 21 (9.52%) 2
Tremor subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Blood and lymphatic system disorders			
Leukopenia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 6 (16.67%) 1	0 / 21 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	16 / 25 (64.00%) 25	3 / 6 (50.00%) 4	12 / 21 (57.14%) 15
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 4	2 / 6 (33.33%) 2	6 / 21 (28.57%) 6
Neutropenia subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 6	1 / 6 (16.67%) 1	5 / 21 (23.81%) 6
Thrombocytosis subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Ear and labyrinth disorders			
Deafness unilateral subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Ear pain			

subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Eye disorders			
Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Glaucoma subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Iridocyclitis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Photophobia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3	1 / 6 (16.67%) 1	3 / 21 (14.29%) 3
Abdominal distension subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Abdominal discomfort			

subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Abdominal pain lower			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 25 (8.00%)	2 / 6 (33.33%)	1 / 21 (4.76%)
occurrences (all)	2	2	1
Ascites			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Anorectal discomfort			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	4 / 25 (16.00%)	1 / 6 (16.67%)	5 / 21 (23.81%)
occurrences (all)	8	1	6
Diarrhoea			
subjects affected / exposed	3 / 25 (12.00%)	2 / 6 (33.33%)	5 / 21 (23.81%)
occurrences (all)	4	2	9
Dry mouth			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Flatulence			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Eructation			

subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Gastritis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	7 / 25 (28.00%)	4 / 6 (66.67%)	12 / 21 (57.14%)
occurrences (all)	10	4	14
Oral pain			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Oesophagitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Oesophageal pain			

subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Saliva altered			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Small intestinal obstruction			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Small intestinal perforation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Tongue pigmentation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 25 (16.00%)	1 / 6 (16.67%)	10 / 21 (47.62%)
occurrences (all)	4	1	15
Hepatobiliary disorders			

Gallbladder obstruction			
subjects affected / exposed	0 / 25 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hepatomegaly			
subjects affected / exposed	0 / 25 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 25 (4.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Ecchymosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	1 / 6 (16.67%) 1	1 / 21 (4.76%) 1
Rash subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Rash maculo-papular subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Xanthoma subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Renal and urinary disorders			
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Renal colic subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Proteinuria subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 6 (16.67%) 1	0 / 21 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Nocturia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0

Urethral stenosis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Urinary retention subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	1 / 6 (16.67%) 2	1 / 21 (4.76%) 1
Back pain subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 4	1 / 6 (16.67%) 1	1 / 21 (4.76%) 1
Flank pain subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Groin pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Muscle tightness			

subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Musculoskeletal pain subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Osteopenia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 2	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Myalgia subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
COVID-19 subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Groin abscess subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Gastroenteritis viral subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 6 (16.67%) 1	0 / 21 (0.00%) 0
Cystitis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0

Groin infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infected bite			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	2 / 25 (8.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	3	0	1
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	2 / 25 (8.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	4	0	0
Sinusitis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0

Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Tooth infection subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 5	1 / 6 (16.67%) 1	8 / 21 (38.10%) 8
Dehydration subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 6 (16.67%) 1	0 / 21 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 6 (16.67%) 1	0 / 21 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	1 / 21 (4.76%) 1
Hypernatraemia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 6 (0.00%) 0	0 / 21 (0.00%) 0
Hypoalbuminaemia			

subjects affected / exposed	0 / 25 (0.00%)	1 / 6 (16.67%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Hypomagnesaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 6 (16.67%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Vitamin D deficiency			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 25 (0.00%)	0 / 6 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose Expansion: Ovarian Cancer	Dose Expansion: SCLC	Dose Expansion: TNBC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	22 / 22 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malignant ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			

subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Capillary fragility			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral venous disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 22 (9.09%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 4 (0.00%)	2 / 22 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	3 / 4 (75.00%)	13 / 22 (59.09%)	0 / 1 (0.00%)
occurrences (all)	3	19	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Sluggishness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 4 (50.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Vascular device occlusion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Reproductive system and breast disorders Nipple pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Aphonia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	5 / 22 (22.73%) 6	0 / 1 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 22 (9.09%) 2	0 / 1 (0.00%) 0
Haemoptysis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Dyspnoea exertional subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Dyspnoea			

subjects affected / exposed	0 / 4 (0.00%)	2 / 22 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Increased bronchial secretion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	2 / 22 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Nasal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Wheezing subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Hallucination subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	1 / 1 (100.00%) 1
Depression subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Investigations			
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	1 / 1 (100.00%) 2
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Blood calcium decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	1 / 1 (100.00%) 1
Blood creatinine increased			

subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	7 / 22 (31.82%)	0 / 1 (0.00%)
occurrences (all)	0	11	0
Platelet count decreased			
subjects affected / exposed	1 / 4 (25.00%)	9 / 22 (40.91%)	1 / 1 (100.00%)
occurrences (all)	1	14	6
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	4 / 22 (18.18%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Injury, poisoning and procedural complications			
Compression fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Contusion			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	1 / 1 (100.00%) 1
Procedural pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Radius fracture subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Cardiac disorders			
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Aortic valve disease subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Nervous system disorders			
Balance disorder subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Areflexia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Aphasia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Cognitive disorder			

subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Dizziness postural			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	1 / 4 (25.00%)	4 / 22 (18.18%)	1 / 1 (100.00%)
occurrences (all)	3	6	1
Dysgeusia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Dysarthria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Multiple sclerosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mental impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lethargy			

subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Paraparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	3 / 22 (13.64%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Taste disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	2 / 4 (50.00%)	13 / 22 (59.09%)	1 / 1 (100.00%)
occurrences (all)	4	18	4
Lymphadenopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1

Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	2 / 4 (50.00%)	6 / 22 (27.27%)	0 / 1 (0.00%)
occurrences (all)	5	12	0
Neutropenia			
subjects affected / exposed	3 / 4 (75.00%)	6 / 22 (27.27%)	1 / 1 (100.00%)
occurrences (all)	3	7	5
Thrombocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Ocular hyperaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Glaucoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Vitreous floaters			

subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 4 (25.00%)	2 / 22 (9.09%)	1 / 1 (100.00%)
occurrences (all)	1	2	1
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Anal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cheilitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Constipation			
subjects affected / exposed	2 / 4 (50.00%)	6 / 22 (27.27%)	0 / 1 (0.00%)
occurrences (all)	2	6	0
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	3 / 22 (13.64%)	1 / 1 (100.00%)
occurrences (all)	4	6	1
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	3 / 22 (13.64%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Eructation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gingival bleeding			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Haemorrhoidal haemorrhage subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 2	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Hypoaesthesia oral subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	4 / 4 (100.00%) 4	12 / 22 (54.55%) 20	1 / 1 (100.00%) 1
Oral pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Oesophagitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Oesophageal pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Odynophagia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 22 (9.09%) 2	0 / 1 (0.00%) 0
Regurgitation subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Upper gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Saliva altered subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Salivary hypersecretion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0

Small intestinal obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Small intestinal perforation subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 2	3 / 22 (13.64%) 3	0 / 1 (0.00%) 0
Tongue pigmentation subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 2	7 / 22 (31.82%) 12	0 / 1 (0.00%) 0
Hepatobiliary disorders Gallbladder obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Hepatomegaly subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Hypertransaminaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Ecchymosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Xanthoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urethral stenosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	3 / 22 (13.64%)	0 / 1 (0.00%)
occurrences (all)	1	4	0
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	5 / 22 (22.73%)	0 / 1 (0.00%)
occurrences (all)	1	5	0
Flank pain			

subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 22 (9.09%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0

COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Groin abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Groin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Infected bite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	1 / 1 (100.00%)
occurrences (all)	0	1	1

Lower respiratory tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Oropharyngeal candidiasis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 3	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 22 (9.09%) 2	0 / 1 (0.00%) 0
Tooth infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 22 (4.55%) 1	0 / 1 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	3 / 4 (75.00%) 3	11 / 22 (50.00%) 12	0 / 1 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 22 (0.00%) 0	0 / 1 (0.00%) 0
Gout			

subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 22 (4.55%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			

subjects affected / exposed	0 / 4 (0.00%)	0 / 22 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose Escalation: Pamiparib + TMZ 20 mg (Days 1-28)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Malignant ascites			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Infected neoplasm			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Cancer pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Capillary fragility			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Deep vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Hypotension			

subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Peripheral venous disease			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Axillary pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Chills			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Early satiety			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	4 / 14 (28.57%)		
occurrences (all)	6		
Gait disturbance			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Localised oedema			

<p>subjects affected / exposed occurrences (all)</p> <p>Oedema peripheral subjects affected / exposed occurrences (all)</p> <p>Sluggishness subjects affected / exposed occurrences (all)</p> <p>Pyrexia subjects affected / exposed occurrences (all)</p> <p>Peripheral swelling subjects affected / exposed occurrences (all)</p> <p>Pain subjects affected / exposed occurrences (all)</p> <p>Vascular device occlusion subjects affected / exposed occurrences (all)</p>	<p>0 / 14 (0.00%) 0</p> <p>0 / 14 (0.00%) 0</p> <p>0 / 14 (0.00%) 0</p> <p>1 / 14 (7.14%) 1</p> <p>1 / 14 (7.14%) 1</p> <p>0 / 14 (0.00%) 0</p> <p>0 / 14 (0.00%) 0</p>		
<p>Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)</p>	<p>0 / 14 (0.00%) 0</p>		
<p>Reproductive system and breast disorders Nipple pain subjects affected / exposed occurrences (all)</p> <p>Heavy menstrual bleeding subjects affected / exposed occurrences (all)</p>	<p>0 / 14 (0.00%) 0</p> <p>0 / 14 (0.00%) 0</p>		
<p>Respiratory, thoracic and mediastinal disorders Aphonia subjects affected / exposed occurrences (all)</p> <p>Cough</p>	<p>0 / 14 (0.00%) 0</p>		

subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Dysphonia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Dyspnoea exertional			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	2		
Dyspnoea			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Hiccups			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Increased bronchial secretion			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Hypoxia			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Increased upper airway secretion			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Pulmonary embolism			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Pleural effusion			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Nasal inflammation subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Nasal congestion subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Sinus congestion subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Rhinitis allergic subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2		
Wheezing subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Hallucination subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Anxiety subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Depression subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Investigations			
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Blood calcium decreased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	4		
Platelet count decreased			
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	7		
Weight decreased			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
White blood cell count decreased			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	3		

Injury, poisoning and procedural complications			
Compression fracture			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Foot fracture			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Fibula fracture			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Radius fracture			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Aortic valve disease			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Tachycardia			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Nervous system disorders			
Balance disorder			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Areflexia			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Aphasia			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Cognitive disorder			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Depressed level of consciousness			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Dizziness			
subjects affected / exposed occurrences (all)	4 / 14 (28.57%) 4		
Dizziness postural			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Dysaesthesia			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Headache			
subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2		
Dysgeusia			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Dysarthria			
subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		

Hemiparesis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Multiple sclerosis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Mental impairment			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Lumbar radiculopathy			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Paraparesis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Parosmia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Peripheral motor neuropathy			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Taste disorder			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		

Tremor subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Blood and lymphatic system disorders			
Leukopenia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Anaemia subjects affected / exposed occurrences (all)	6 / 14 (42.86%) 10		
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Lymphopenia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Neutropenia subjects affected / exposed occurrences (all)	3 / 14 (21.43%) 4		
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Ear and labyrinth disorders			
Deafness unilateral subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Ear pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Vertigo subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 2		
Eye disorders			

Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Glaucoma subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Cataract subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Iridocyclitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Vision blurred subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Photophobia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Abdominal distension subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Abdominal pain upper			

subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Anorectal discomfort			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Anal inflammation			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Cheilitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	6 / 14 (42.86%)		
occurrences (all)	6		
Diarrhoea			
subjects affected / exposed	3 / 14 (21.43%)		
occurrences (all)	3		
Dry mouth			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Flatulence			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Eructation			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Gastritis			

subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Haematochezia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Gingival bleeding			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Hypoaesthesia oral			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	6 / 14 (42.86%)		
occurrences (all)	8		
Oral pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Oesophagitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Oesophageal pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Odynophagia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Regurgitation			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Toothache subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Upper gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Saliva altered subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Salivary hypersecretion subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Small intestinal obstruction subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Small intestinal perforation subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Stomatitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Tongue pigmentation subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2		
Hepatobiliary disorders Gallbladder obstruction subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Hepatomegaly subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		

Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Dry skin subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Ecchymosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Nail discolouration subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Onychoclasia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Nail disorder subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Pruritus subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Rash subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Rash maculo-papular			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Xanthoma subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Renal and urinary disorders			
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Dysuria subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Haematuria subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Renal colic subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Proteinuria subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Pollakiuria subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Nocturia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Urethral stenosis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Urinary retention subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		

Urinary incontinence subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Back pain subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Flank pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Groin pain subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Muscle spasms subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Muscular weakness subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Muscle tightness subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Musculoskeletal pain subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Pain in extremity			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Osteopenia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Neck pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Myalgia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
COVID-19 subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Groin abscess subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Gastroenteritis viral subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Cystitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Groin infection subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Influenza subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		

Infected bite			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Oral herpes			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Onychomycosis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		

Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Tooth infection subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	5 / 14 (35.71%) 8		
Dehydration subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2		
Gout subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Hypercalcaemia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Hyperkalaemia subjects affected / exposed occurrences (all)	3 / 14 (21.43%) 6		
Hypernatraemia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Hypomagnesaemia			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1		
Hypocalcaemia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 2		
Hypophosphataemia subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 3		
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		
Vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 March 2017	Version 1.0
15 December 2017	Protocol Amendment 1.1 (UK)
25 February 2020	Protocol Amendment 2.0
19 June 2020	Protocol Amendment 3.0

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported