Clinical trial results:
An open-label, first-in-human, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and maximum tolerated dose and / or recommended Phase II dose of the ATR inhibitor BAY 1895344 in patients with advanced solid tumors and lymphomas.

Summary

EudraCT number	2016-004484-39
Trial protocol	GB FR
Global end of trial date	13 September 2023

Results information

Result version number	v1 (current)
This version publication date	02 June 2024
First version publication date	02 June 2024

Trial information

Trial identification

Sponsor protocol code	18594

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03188965
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser Wilhelm Allee, Leverkusen, Germany, D-51368
Public contact	Therapeutic Area Head, Bayer AG, +49 30 300139003 , clinical-trials-contact@bayer.com
Scientific contact	Therapeutic Area Head, Bayer AG, +49 30 300139003 , clinical-trials-contact@bayer.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	19 October 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 September 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Determine the maximum tolerated dose (MTD) and / or recommended Phase II dose (RP2D), safety, tolerability, and pharmacokinetics (PK) of BAY 1895344 as single agent, in patients with advanced solid tumors and lymphomas.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and the International Council for Harmonization guideline E6: Good Clinical Practice. Before entering the study, the informed consent was read by and explained to all the subjects. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 July 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 129
Country: Number of subjects enrolled	Switzerland: 137
Country: Number of subjects enrolled	Japan: 85
Country: Number of subjects enrolled	Singapore: 101
Country: Number of subjects enrolled	United States: 306
Country: Number of subjects enrolled	Canada: 123
Country: Number of subjects enrolled	China: 24
Worldwide total number of subjects	905
EEA total number of subjects	0

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)	577
From 65 to 84 years	324
85 years and over	4

Subject disposition

Recruitment

Recruitment details:

The study was conducted in in 5 countries in Part A, 6 countries in Part A.1, 7 countries in Part B, and 2 countries in Part B.1 between 06 July 2017 (first subject first visit) and 13 September 2023 (last subject last visit).

Pre-assignment

Screening details:

54 of 65 (Part A, including 8 in J-arm), 32 of 87 (Part A1) and 143 of 753 (Part B) subjects who signed ICF were assigned to study intervention. Neither of the 2 subjects who signed ICF in Part B.1 were assigned to study intervention.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A - 5mg BID

Arm description:

Subjects received elimusertib 5 mg 2 times daily (BID) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 5 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 5 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A - 10mg BID

Arm description:

Subjects received elimusertib 10 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Arm type	Experimental

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 10 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 10 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A - 20mg BID Pooled

Arm description:

Subjects received elimusertib 20 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 20 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation;20 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A - 40mg BID MTD

Arm description:

Subjects received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A - 40mg BID Non-MTD

Arm description:

Subjects, who were not included in the maximum tolerated dose (MTD) analysis, received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A - 60mg BID

Arm description:

Subjects received elimusertib 60 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 60 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 60 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A - 60mg BID 2w/1w

Arm description:

Subjects received elimusertib 60 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with 2 weeks on/1 week off in Part A of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 60 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with 2 weeks on/1 week off, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 60 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with 2 weeks on/1 week off, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A - 80mg BID

Arm description:

Subjects received elimusertib 80 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 80 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 80 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A.1 - 60mg BID 3d/11d

Arm description:

Subjects received elimusertib 60 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 60 mg (BID, every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A.1 - 80mg BID 3d/11d

Arm description:

Subjects received elimusertib 80 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 80 mg (BID, every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A.1 - 100mg BID 3d/11d

Arm description:

Subjects received elimusertib 100 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 100 mg (BID, every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part A.1 - 120mg BID 3d/11d

Arm description:

Subjects received elimusertib 120 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 120 mg (BID, every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part B - Prostate

Arm description:

Subjects with prostate cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part B - Colorectal

Arm description:

Subjects with colorectal cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution

Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part B - Gynecological

Arm description:

Subjects with gynecological cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part B - Breast

Arm description:

Subjects with breast cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Liquid service formulation; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Arm title	Part B - ATM loss

Arm description:

Subjects with ATM loss regardless of cancer type received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Arm type	Experimental
Investigational medicinal product name	Elimusertib
Investigational medicinal product code	BAY1895344
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; 40 mg BID (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles, until evidence of tumor progression, unacceptable toxicity, consent withdrawal, or withdrawal from the study at the discretion of the investigator.

Number of subjects in period 1[1]	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled
Started	1	2	6
Completed	0	0	0
Not completed	1	2	6
Physician decision	-	-	1
Consent withdrawn by subject	-	-	-
Progressive disease - clinical progression	-	-	-
Other	-	-	-
Adverse event	-	-	-
Progressive disease	1	2	5

Number of subjects in period 1[1]	Part A - 40mg BID MTD	Part A - 40mg BID Non-MTD	Part A - 60mg BID
Started	6	24	8
Completed	0	0	0
Not completed	6	24	8
Physician decision	-	1	-
Consent withdrawn by subject	-	-	-
Progressive disease - clinical progression	1	4	1
Other	-	-	-
Adverse event	-	3	1
Progressive disease	5	16	6

Number of subjects in period 1[1]	Part A - 60mg BID 2w/1w	Part A - 80mg BID	Part A.1 - 60mg BID 3d/11d
Started	4	3	6

Completed	0	0	0
Not completed	4	3	6
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Progressive disease - clinical progression	1	-	1
Other	-	-	-
Adverse event	-	1	-
Progressive disease	3	2	5

Number of subjects in period 1[1]	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Started	11	6	9
Completed	0	0	0
Not completed	11	6	9
Physician decision	-	-	-
Consent withdrawn by subject	-	-	1
Progressive disease - clinical progression	-	1	2
Other	-	-	-
Adverse event	-	-	2
Progressive disease	11	5	4

Number of subjects in period 1[1]	Part B - Prostate	Part B - Colorectal	Part B - Gynecological
Started	19	24	45
Completed	0	0	0
Not completed	19	24	45
Physician decision	-	-	1
Consent withdrawn by subject	1	1	1
Progressive disease - clinical progression	5	2	7
Other	-	1	-
Adverse event	1	2	8
Progressive disease	12	18	28

Number of subjects in period 1[1]	Part B - Breast	Part B - ATM loss
Started	19	36
Completed	0	0
Not completed	19	36
Physician decision	-	-
Consent withdrawn by subject	1	4
Progressive disease - clinical progression	3	6
Other	-	-

Adverse event	3	5
Progressive disease	12	21

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Of the 65 (Part A), 87 (Part A.1) 751 (Part B) and 2 (Part B.1) enrolled subjects, only 54 (Part A), 32 (Part A.1), 143 (Part B) subjects completed general screening and were assigned to study intervention.

Reporting groups	
Reporting group title	Part A - 5mg BID
Reporting group description:	
Subjects received elimusertib 5 mg 2 times daily (BID) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 10mg BID
Reporting group description:	
Subjects received elimusertib 10 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 20mg BID Pooled
Reporting group description:	
Subjects received elimusertib 20 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 40mg BID MTD
Reporting group description:	
Subjects received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 40mg BID Non-MTD
Reporting group description:	
Subjects, who were not included in the maximum tolerated dose (MTD) analysis, received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 60mg BID
Reporting group description:	
Subjects received elimusertib 60 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 60mg BID 2w/1w
Reporting group description:	
Subjects received elimusertib 60 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with 2 weeks on/1 week off in Part A of the study.	
Reporting group title	Part A - 80mg BID
Reporting group description:	
Subjects received elimusertib 80 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A.1 - 60mg BID 3d/11d
Reporting group description:	
Subjects received elimusertib 60 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.	
Reporting group title	Part A.1 - 80mg BID 3d/11d
Reporting group description:	
Subjects received elimusertib 80 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.	
Reporting group title	Part A.1 - 100mg BID 3d/11d
Reporting group description:	
Subjects received elimusertib 100 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.	
Reporting group title	Part A.1 - 120mg BID 3d/11d
Reporting group description:	
Subjects received elimusertib 120 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.	
Reporting group title	Part B - Prostate
Reporting group description:	
Subjects with prostate cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly	

schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - Colorectal

Reporting group description:

Subjects with colorectal cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - Gynecological

Reporting group description:

Subjects with gynecological cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - Breast

Reporting group description:

Subjects with breast cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - ATM loss

Reporting group description:

Subjects with ATM loss regardless of cancer type received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group values	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled
Number of subjects	1	2	6
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	73.0	67.0	65.5
standard deviation	± 0	± 4.2	± 5.4
Gender categorical Units: Subjects			
Female	0	0	0
Male	1	2	6

Reporting group values	Part A - 40mg BID MTD	Part A - 40mg BID Non-MTD	Part A - 60mg BID
Number of subjects	6	24	8
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	53.0	62.8	61.0
standard deviation	± 16.5	± 12.1	± 7.1
Gender categorical Units: Subjects			
Female	4	14	6
Male	2	10	2

Reporting group values	Part A - 60mg BID 2w/1w	Part A - 80mg BID	Part A.1 - 60mg BID 3d/11d
Number of subjects	4	3	6

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	58.5	51.0	57.7
standard deviation	± 6.9	± 8.7	± 10.1
Gender categorical Units: Subjects			
Female	1	3	2
Male	3	0	4

Reporting group values	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Number of subjects	11	6	9
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	59.3	58.2	63.4
standard deviation	± 14.3	± 11.1	± 12.1
Gender categorical Units: Subjects			
Female	2	3	2
Male	9	3	7

Reporting group values	Part B - Prostate	Part B - Colorectal	Part B - Gynecological
Number of subjects	19	24	45
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	69.1	55.6	56.4
standard deviation	± 7.7	± 12.5	± 9.5
Gender categorical Units: Subjects			
Female	0	9	45
Male	19	15	0

Reporting group values	Part B - Breast	Part B - ATM loss	Total
Number of subjects	19	36	229
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	49.8	57.6	
standard deviation	± 8.2	± 11.1	-

Gender categorical Units: Subjects			
Female	19	15	125
Male	0	21	104

End points

End points reporting groups

Reporting group title	Part A - 5mg BID
Reporting group description:	
Subjects received elimusertib 5 mg 2 times daily (BID) for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 10mg BID
Reporting group description:	
Subjects received elimusertib 10 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 20mg BID Pooled
Reporting group description:	
Subjects received elimusertib 20 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 40mg BID MTD
Reporting group description:	
Subjects received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 40mg BID Non-MTD
Reporting group description:	
Subjects, who were not included in the maximum tolerated dose (MTD) analysis, received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 60mg BID
Reporting group description:	
Subjects received elimusertib 60 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A - 60mg BID 2w/1w
Reporting group description:	
Subjects received elimusertib 60 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with 2 weeks on/1 week off in Part A of the study.	
Reporting group title	Part A - 80mg BID
Reporting group description:	
Subjects received elimusertib 80 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.	
Reporting group title	Part A.1 - 60mg BID 3d/11d
Reporting group description:	
Subjects received elimusertib 60 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.	
Reporting group title	Part A.1 - 80mg BID 3d/11d
Reporting group description:	
Subjects received elimusertib 80 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.	
Reporting group title	Part A.1 - 100mg BID 3d/11d
Reporting group description:	
Subjects received elimusertib 100 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.	
Reporting group title	Part A.1 - 120mg BID 3d/11d
Reporting group description:	
Subjects received elimusertib 120 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.	
Reporting group title	Part B - Prostate
Reporting group description:	
Subjects with prostate cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly	

schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - Colorectal

Reporting group description:

Subjects with colorectal cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - Gynecological

Reporting group description:

Subjects with gynecological cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - Breast

Reporting group description:

Subjects with breast cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - ATM loss

Reporting group description:

Subjects with ATM loss regardless of cancer type received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Subject analysis set title	MTD analysis set - Part A (non-Japanese)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Maximum tolerated dose (MTD) analysis set - Part A (non-Japanese) included all (non-Japanese) subjects used to determine the MTD in Part A. Subjects in Part A who started treatment when the MTD was already determined at 40 mg BID were excluded from the MTD analysis set.

Subject analysis set title	MTD analysis set - Part A (J-arm)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Maximum tolerated dose (MTD) analysis set - Part A (J-arm) included all Japanese subjects used to determine the MTD in Japanese patients in Part A.

Subject analysis set title	MTD analysis set - Part A.1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Maximum tolerated dose (MTD) analysis set - Part A.1 included all patients used to determine the MTD in Part A.1.

Subject analysis set title	Part A - J-arm 20mg BID
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part A - J-arm 20mg BID included all Japanese subjects who received elimusertib 20 mg 2 times daily (BID) (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule (in a 21-day cycle) with no break between cycles.

Subject analysis set title	Part A - non-J 20mg BID
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part A - non-J 20mg BID included all non-Japanese subjects who received elimusertib 20 mg 2 times daily (BID) (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule (in a 21-day cycle) with no break between cycles.

Subject analysis set title	Part A - J-arm 40mg BID
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part A - J-arm 40mg BID included all Japanese subjects who received elimusertib 40 mg 2 times daily (BID) (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule (in a 21-day cycle) with no break between cycles.

Subject analysis set title	Part A - non-J 40mg BID
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Part A - non-J 40mg BID included all non-Japanese subjects who received elimusertib 40 mg 2 times daily (BID) (every 12±1 hours, except on Cycle 1 Day 1 when elimusertib was administered once daily) for 3 days on/4 days off in a weekly schedule (in a 21-day cycle) with no break between cycles.

Subject analysis set title	Safety analysis set (SAF)
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects who received at least 1 dose of elimusertib and had post treatment safety data available were included in the safety evaluation.

Subject analysis set title	Efficacy analysis set (EAS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All subjects who received at least 1 dose of elimusertib and who had postbaseline efficacy data available and no important protocol deviations affecting validity were included in the efficacy evaluation. This included subjects with death due to any cause or clinical disease progression before the first postbaseline response assessment.

Subject analysis set title	PK analysis set (PKS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All subjects who had received at least 1 dose of elimusertib and with at least 1 valid concentration of elimusertib after first dosing and no important protocol deviations affecting the validity were included in the PK evaluation.

Subject analysis set title	Part B PKS
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All subjects in Part B who had received at least 1 dose of elimusertib and with at least 1 valid concentration of elimusertib after first dosing and no important protocol deviations affecting the validity were included in the PK evaluation.

Primary: Number of subjects with dose-limiting toxicities (DLTs) during Cycle 1 in dose escalation cohorts

End point title	Number of subjects with dose-limiting toxicities (DLTs) during Cycle 1 in dose escalation cohorts[1][2]

End point description:

A DLT was defined as any of those hematological, non-hematological or miscellaneous TEAEs that listed in the study protocol that were related to BAY 1895344 for Part A, J-arm of Part A, and Part A.1, and occurring during Cycle 1 of a dose level. SAF was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

21 days (Cycle 1) in Part A and 28 days (Cycle 1) in Part A.1

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: Due to the nature of this trial, only descriptive statistics were performed for DLTs. No inferential statistical analyses were pre-specified.
[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: The analyses of DLTs were only planned for Part A and Part A.1 of the study.

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled	Part A - 40mg BID MTD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	6	6
Units: Subject(s)	0	0	0	0

End point values	Part A - 40mg BID Non-MTD	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	8	4	3
Units: Subject(s)	0	2	2	2

End point values	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	11	6	9
Units: Subject(s)	0	0	0	2

End point values	Part A - J-arm 20mg BID	Part A - non-J 20mg BID	Part A - J-arm 40mg BID	Part A - non-J 40mg BID
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	2	4	2
Units: Subject(s)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Maximum tolerated dose (MTD)

End point title	Maximum tolerated dose (MTD)[3]

End point description:

The MTD was defined as the maximum dose at which the incidence of dose-limiting toxicities (DLTs) during Cycle 1 was below 30%, or the maximum dose tested, whichever was achieved first during dose escalation. The MTD for the 3 days on/4 days off dosing schedule was to be determined in Part A non-Japanese subjects and the safety and tolerability of the established MTD was to be evaluated in Part A Japanese subjects (J-arm). The MTD for the 3 days on/11 days off dosing schedule was planned to be determined in Part A.1. MTD analysis set was used for the analysis of this endpoint. "99999" denotes that MTD could not be formally identified due to no DLTs that met protocol-specified criteria were observed.

End point type	Primary

End point timeframe:

21 days (Cycle 1)

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: Due to the nature of this trial, only descriptive statistics were performed for MTD. No inferential statistical analyses were pre-specified.

End point values	MTD analysis set - Part A (non-Japanese)	MTD analysis set - Part A (J-arm)	MTD analysis set - Part A.1	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	7	29	
Units: milligram(s)				
number (not applicable)				

3 days on/4 days off	40	40	99999	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with treatment-emergent adverse events

End point title	Number of subjects with treatment-emergent adverse events[4]

End point description:

An adverse event (AE) was any untoward medical occurrence in a subject, associated with the use of study intervention, whether or not considered related to the study intervention. A serious adverse event (SAE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening; persistent or significant disability/incapacity; congenital anomaly/birth defect; another medical important serious event as judged by the investigator. AEs or SAEs were considered to be treatment emergent (TEAEs or TESAEs) if they started or worsened after first administration of study drug up to 30 days after the last dose of study drug. SAF was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

After first administration of study drug up to 30 days after the last dose of study drug

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: Due to the nature of this trial, only descriptive statistics were performed for TEAEs. No inferential statistical analyses were pre-specified.

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled	Part A - 40mg BID MTD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	6	6
Units: Subject(s)				
Any TEAE	1	2	6	6
Any TESAE	0	1	1	1
Any elimusertib related TEAE	1	2	5	6
Any elimusertib related TESAE	0	1	0	0

End point values	Part A - 40mg BID Non-MTD	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	8	4	3
Units: Subject(s)				
Any TEAE	24	8	4	3
Any TESAE	7	5	2	2
Any elimusertib related TEAE	22	8	4	3
Any elimusertib related TESAE	1	1	0	1

End point values	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	11	6	9
Units: Subject(s)				
Any TEAE	6	10	6	9
Any TESAE	3	4	3	5
Any elimusertib related TEAE	6	9	6	8
Any elimusertib related TESAE	0	0	1	1

End point values	Part B - Prostate	Part B - Colorectal	Part B - Gynecological	Part B - Breast
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	24	45	19
Units: Subject(s)				
Any TEAE	19	24	45	19
Any TESAE	4	14	21	5
Any elimusertib related TEAE	18	22	45	18
Any elimusertib related TESAE	0	2	6	1

End point values	Part B - ATM loss			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Subject(s)				
Any TEAE	36			
Any TESAE	14			
Any elimusertib related TEAE	33			
Any elimusertib related TESAE	0			

Statistical analyses

No statistical analyses for this end point

Primary: Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]) after single-dose administration (n=3 or higher)

End point title	Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]) after single-dose administration (n=3 or higher)[5][6]

End point description:

Results of AUC(0-12) after single dose of the noncompartmental analysis are reported below. Geometric mean and coefficient of variation (CV%) are presented for reporting groups with at least 3 subjects

analyzed (n=3). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 60mg BID	Part A - 80mg BID	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	3	5	11
Units: µg·h/L				
geometric mean (geometric coefficient of variation)	13400 (± 30.1)	19600 (± 27.2)	8990 (± 31.2)	13500 (± 29.3)

End point values	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d	Part A - J-arm 20mg BID	Part A - J-arm 40mg BID
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	6	9	4	4
Units: µg·h/L				
geometric mean (geometric coefficient of variation)	14300 (± 18.3)	18700 (± 40.7)	3870 (± 28.6)	9110 (± 30.0)

End point values	Part B PKS			
Subject group type	Subject analysis set			
Number of subjects analysed	87			
Units: µg·h/L				
geometric mean (geometric coefficient of variation)	7350 (± 32.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]) after single-dose administration (n=2)

End point title	Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]) after single-dose administration (n=2)[7]

End point description:

Results of AUC(0-12) after single dose of the noncompartmental analysis are reported below. Median and range are presented for reporting groups with 2 subjects analyzed (n=2). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.

End point values	Part A - non-J 20mg BID	Part A - non-J 40mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	2		
Units: µg·h/L				
median (full range (min-max))	4350 (3340 to 5360)	8390 (7180 to 9610)		

Statistical analyses

No statistical analyses for this end point

Primary: Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]) after single-dose administration (n=1)

End point title	Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]) after single-dose administration (n=1)[8][9]

End point description:

Results of AUC(0-12) after single dose of the noncompartmental analysis are reported below. Individual value is presented for reporting groups with only 1 subject analyzed (n=1). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[8] - 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: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[9] - 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: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 5mg BID	Part A - 10mg BID		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: µg·h/L				
number (not applicable)	934	1590		

Statistical analyses

No statistical analyses for this end point

Primary: Maximum observed drug concentration in plasma after single-dose administration (Cmax) (n=3 or higher)

End point title	Maximum observed drug concentration in plasma after single-dose administration (Cmax) (n=3 or higher)[10][11]

End point description:

Results of Cmax after single dose of the noncompartmental analysis are reported below. Geometric mean and coefficient of variation (CV%) are presented for reporting groups with at least 3 subjects analyzed (n=3 or higher). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[10] - 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: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[11] - 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: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 60mg BID	Part A - 80mg BID	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	3	5	11
Units: µg/L				
geometric mean (geometric coefficient of variation)	2480 (± 33.4)	3260 (± 26.3)	1470 (± 28.2)	2270 (± 41.8)

End point values	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d	Part A - J-arm 20mg BID	Part A - J-arm 40mg BID
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	6	9	4	4
Units: µg/L				
geometric mean (geometric coefficient of variation)	1740 (± 13.9)	2920 (± 31.0)	667 (± 37.5)	1780 (± 44.3)

End point values	Part B PKS			
Subject group type	Subject analysis set			
Number of subjects analysed	87			
Units: µg/L				
geometric mean (geometric coefficient of variation)	1230 (± 37.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Maximum observed drug concentration in plasma after single-dose administration (Cmax) (n=2)

End point title	Maximum observed drug concentration in plasma after single-dose administration (Cmax) (n=2)[12]

End point description:

Results of Cmax after single dose of the noncompartmental analysis are reported below. Median and range are presented for reporting groups with 2 subjects analyzed (n=2). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[12] - 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: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.

End point values	Part A - non-J 20mg BID	Part A - non-J 40mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	2		
Units: µg/L				
median (full range (min-max))	619 (383 to 855)	1840 (1820 to 1860)		

Statistical analyses

No statistical analyses for this end point

Primary: Maximum observed drug concentration in plasma after single-dose administration (Cmax) (n=1)

End point title	Maximum observed drug concentration in plasma after single-dose administration (Cmax) (n=1)[13][14]

End point description:

Results of Cmax after single dose of the noncompartmental analysis are reported below. Individual value is presented for reporting groups with 1 subject analyzed (n=1). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 5mg BID	Part A - 10mg BID		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: µg/L				
number (not applicable)	178	258		

Statistical analyses

No statistical analyses for this end point

Primary: Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]md) after multiple-dose administrations (n=3 or higher)

End point title	Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]md) after multiple-dose administrations (n=3 or higher)[15][16]

End point description:

Results of AUC(0-12) after the 5th dose of the noncompartmental analysis are reported below. Geometric mean and coefficient of variation (CV%) are presented for reporting groups with at least 3 subjects analyzed (n=3 or higher). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 60mg BID	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	9	3
Units: µg·h/L				
geometric mean (geometric coefficient of variation)	18800 (± 52.9)	20900 (± 34.8)	24700 (± 37.2)	29100 (± 45.1)

End point values	Part A.1 - 120mg BID 3d/11d	Part A - J-arm 20mg BID	Part A - J-arm 40mg BID	Part B PKS
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	4	4	65
Units: µg·h/L				
geometric mean (geometric coefficient of variation)	36700 (± 47.5)	6910 (± 40.9)	16400 (± 27.8)	12300 (± 46.2)

Statistical analyses

No statistical analyses for this end point

Primary: Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]md) after multiple-dose administrations (n=1)

End point title	Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]md) after multiple-dose administrations (n=1)[17][18]

End point description:

Results of AUC(0-12) after the 5th dose of the noncompartmental analysis are reported below. Individual value is presented for reporting groups with 1 subject analyzed (n=1). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - non-J 20mg BID	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	1	1	1	
Units: µg·h/L				
number (not applicable)	1600	2450	8050	

Statistical analyses

No statistical analyses for this end point

Primary: Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]md) after multiple-dose administrations (n=2)

End point title	Area under the plasma concentration versus time curve from 0 to 12 hours (AUC[0-12]md) after multiple-dose administrations (n=2)[19][20]

End point description:

Results of AUC(0-12) after the 5th dose of the noncompartmental analysis are reported below. Median and range are presented for reporting groups with 2 subjects analyzed (n=2). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 80mg BID	Part A - non-J 40mg BID		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	2	2		
Units: µg·h/L				
median (full range (min-max))	39900 (19300 to 60500)	13400 (11400 to 15300)		

Statistical analyses

No statistical analyses for this end point

Primary: Maximum observed drug concentration in plasma after multiple-dose administrations (Cmax,md) (n=3 or higher)

End point title	Maximum observed drug concentration in plasma after multiple-dose administrations (Cmax,md) (n=3 or higher)[21][22]

End point description:

Results of Cmax after the 5th dose of the noncompartmental analysis are reported below. Geometric mean and coefficient of variation (CV%) are presented for reporting groups with at least 3 subjects analyzed (n=3 or higher). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 60mg BID	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	9	3
Units: µg/L				
geometric mean (geometric coefficient of variation)	3280 (± 54.7)	2110 (± 42.1)	3280 (± 36.6)	3540 (± 30.2)

End point values	Part A.1 - 120mg BID 3d/11d	Part A - J-arm 20mg BID	Part A - J-arm 40mg BID	Part B PKS
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	4	4	65
Units: µg/L				
geometric mean (geometric coefficient of variation)	4490 (± 38.4)	1020 (± 52.4)	2640 (± 44.1)	1750 (± 44.7)

Statistical analyses

No statistical analyses for this end point

Primary: Maximum observed drug concentration in plasma after multiple-dose administrations (Cmax,md) (n=2)

End point title	Maximum observed drug concentration in plasma after multiple-dose administrations (Cmax,md) (n=2)[23][24]

End point description:

Results of Cmax after the 5th dose of the noncompartmental analysis are reported below. Median and range are presented for reporting groups with 2 subjects analyzed (n=2). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 80mg BID	Part A - non-J 40mg BID		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	2	2		
Units: µg/L				
median (full range (min-max))	5660 (3330 to 8000)	2280 (2200 to 2360)		

Statistical analyses

No statistical analyses for this end point

Primary: Maximum observed drug concentration in plasma after multiple-dose administrations (Cmax,md) (n=1)

End point title	Maximum observed drug concentration in plasma after multiple-dose administrations (Cmax,md) (n=1)[25][26]

End point description:

Results of Cmax after the 5th dose of the noncompartmental analysis are reported below. Individual value is presented for reporting groups with 1 subject analyzed (n=1). PKS was used for the analysis of this endpoint.

End point type	Primary

End point timeframe:

Pre-dose and up to 12 hours post-dose

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Due to the nature of this trial, only noncompartmental pharmacokinetic analyses were planned as part of the primary endpoint analyses of the study. Dose proportionality, relative bioavailability and food effect were only planned and performed as explorative analyses.
[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic analyses are reported separately per number of subjects analyzed.

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - non-J 20mg BID	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	1	1	1	
Units: µg/L				
number (not applicable)	263	420	1070	

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate (ORR) of solid tumor responses (except CRPC) consistent with the RECIST 1.1

End point title	Objective response rate (ORR) of solid tumor responses (except CRPC) consistent with the RECIST 1.1

End point description:

ORR was defined as the percentage of participants with best overall response of complete response (CR) or partial response (PR) during the course of the study. Best overall responses were evaluated by the investigator as per the RECIST 1.1 (Eisenhauer et al. 2009). EAS was used for the analysis. CRPC: castration-resistant prostate cancer; RECIST: Response Evaluation Criteria in Solid Tumors

End point type	Secondary

End point timeframe:

Part A: up to 1340 days; Part A.1: up to 597 days; Part B: 1361 days

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled	Part A - 40mg BID MTD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	5	6
Units: Percentage				
number (confidence interval 95%)	0 (0 to 97.5)	0 (0 to 97.5)	0 (0 to 52.2)	33.3 (4.3 to 77.7)

End point values	Part A - 40mg BID Non-MTD	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	7	2	3
Units: Percentage				
number (confidence interval 95%)	0 (0 to 16.8)	14.3 (0.4 to 47.9)	0 (0 to 84.2)	33.3 (0.8 to 90.6)

End point values	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	10	5	8
Units: Percentage				
number (confidence interval 95%)	0 (0 to 60.2)	0 (0 to 30.8)	20.0 (0.5 to 71.6)	12.5 (0.3 to 52.7)

End point values	Part B - Prostate	Part B - Colorectal	Part B - Gynecological	Part B - Breast
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[27]	23	42	18
Units: Percentage				
number (confidence interval 95%)	(to)	0 (0 to 14.8)	2.4 (0.1 to 12.6)	11.1 (1.4 to 34.7)

Notes:

[27] - No evaluable subject

End point values	Part B - ATM loss			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: Percentage				
number (confidence interval 95%)	4.3 (0.1 to			

21.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate (ORR) of CRPC tumor responses consistent with the recommendations of PCWG3

End point title	Objective response rate (ORR) of CRPC tumor responses consistent with the recommendations of PCWG3

End point description:

ORR was defined as the percentage of participants with best overall response of complete response (CR) or partial response (PR) or a PSA-based response during the course of the study. Best overall responses were evaluated by the investigator as per the RECIST 1.1 according to the recommendations of PCWG3 (Scher et al. 2016). EAS was used for the analysis. CRPC: castration-resistant prostate cancer; PSA: prostate-specific antigen; RECIST: Response Evaluation Criteria in Solid Tumors; PCWG3: Prostate Cancer Working Group 3

End point type	Secondary

End point timeframe:

Part A: up to 1340 days; Part A.1: up to 597 days; Part B: 1361 days

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled	Part A - 40mg BID MTD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[28]	1	0[29]	0[30]
Units: Percentage				
number (confidence interval 95%)	(to)	0 (0 to 97.5)	(to)	(to)

Notes:

[28] - No evaluable subject

[29] - No evaluable subject

[30] - No evaluable subject

End point values	Part A - 40mg BID Non-MTD	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	2	0[31]
Units: Percentage				
number (confidence interval 95%)	0 (0 to 60.2)	0 (0 to 97.5)	0 (0 to 84.2)	(to)

Notes:

[31] - No evaluable subject

End point values	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	1
Units: Percentage				

number (confidence interval 95%)	0 (0 to 84.2)	0 (0 to 97.5)	0 (0 to 97.5)	0 (0 to 97.5)

End point values	Part B - Prostate	Part B - Colorectal	Part B - Gynecological	Part B - Breast
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	0[32]	0[33]	0[34]
Units: Percentage				
number (confidence interval 95%)	0 (0 to 18.5)	(to)	(to)	(to)

Notes:

[32] - No evaluable subject

[33] - No evaluable subject

[34] - No evaluable subject

End point values	Part B - ATM loss			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Percentage				
number (confidence interval 95%)	20.0 (2.5 to 55.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate (ORR) of lymphoma responses consistent with Lugano Classification

End point title	Objective response rate (ORR) of lymphoma responses consistent with Lugano Classification

End point description:

ORR was defined as the percentage of participants with best overall response of complete response (CR) or partial response (PR) during the course of the study. Best overall responses were to be evaluated by the investigator as per the Lugano Classification (Cheson et al. 2014). EAS was planned to be used for the analysis.

End point type	Secondary

End point timeframe:

0 day as no subject was evaluated as per Lugano Classification

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled	Part A - 40mg BID MTD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[35]	0[36]	0[37]	0[38]
Units: Percentage				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:
[35] - No evaluable subject
[36] - No evaluable subject
[37] - No evaluable subject
[38] - No evaluable subject

End point values	Part A - 40mg BID Non-MTD	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[39]	0[40]	0[41]	0[42]
Units: Percentage				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:
[39] - No evaluable subject
[40] - No evaluable subject
[41] - No evaluable subject
[42] - No evaluable subject

End point values	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[43]	0[44]	0[45]	0[46]
Units: Percentage				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:
[43] - No evaluable subject
[44] - No evaluable subject
[45] - No evaluable subject
[46] - No evaluable subject

End point values	Part B - Prostate	Part B - Colorectal	Part B - Gynecological	Part B - Breast
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[47]	0[48]	0[49]	0[50]
Units: Percentage				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:
[47] - No evaluable subject
[48] - No evaluable subject
[49] - No evaluable subject
[50] - No evaluable subject

End point values	Part B - ATM loss			
Subject group type	Reporting group			
Number of subjects analysed	0[51]			
Units: Percentage				
number (confidence interval 95%)	(to)			

Notes:
[51] - No evaluable subject

Statistical analyses

No statistical analyses for this end point

Secondary: Disease control rate (DCR) of solid tumor responses (except CRPC) consistent with the RECIST 1.1

End point title	Disease control rate (DCR) of solid tumor responses (except CRPC) consistent with the RECIST 1.1

End point description:

DCR was defined as the percentage of subjects with complete response (CR) or partial response (PR) as best overall response, or stable disease (SD) for at least 10 weeks during the course of the study. Best overall responses were evaluated by the investigator as per the RECIST 1.1 (Eisenhauer et al. 2009). EAS was used for the analysis. CRPC: castration-resistant prostate cancer; RECIST: Response Evaluation Criteria in Solid Tumors

End point type	Secondary

End point timeframe:

Part A: up to 1340 days; Part A.1: up to 597 days; Part B: 1361 days

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled	Part A - 40mg BID MTD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	5	6
Units: Percentage				
number (confidence interval 95%)	0 (0 to 97.5)	0 (0 to 97.5)	60.0 (14.7 to 94.7)	50.0 (11.8 to 88.2)

End point values	Part A - 40mg BID Non-MTD	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	7	2	3
Units: Percentage				
number (confidence interval 95%)	45.0 (23.1 to 68.5)	28.6 (3.7 to 71.0)	0 (0 to 84.2)	66.7 (9.4 to 99.2)

End point values	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	10	5	8
Units: Percentage				
number (confidence interval 95%)	50.0 (6.8 to 93.2)	50.0 (18.7 to 81.3)	40.0 (5.3 to 85.3)	25.0 (3.2 to 65.1)

End point values	Part B - Prostate	Part B - Colorectal	Part B - Gynecological	Part B - Breast
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[52]	23	42	18

Units: Percentage				
number (confidence interval 95%)	(to)	47.8 (26.8 to 69.4)	59.5 (43.3 to 74.4)	44.4 (21.5 to 69.2)

Notes:

[52] - No evaluable subject

End point values	Part B - ATM loss			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: Percentage				
number (confidence interval 95%)	52.2 (30.6 to 73.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Disease control rate (DCR) of CRPC tumor responses consistent with the recommendations of PCWG3

End point title	Disease control rate (DCR) of CRPC tumor responses consistent with the recommendations of PCWG3

End point description:

DCR was defined as the percentage of subjects with complete response (CR) or partial response (PR) as best overall response, or stable disease (SD) for at least 10 weeks during the course of the study. Best overall responses were evaluated by the investigator as per the RECIST 1.1 according to the recommendations of PCWG3 (Scher et al. 2016). EAS was used for the analysis. CRPC: castration-resistant prostate cancer; PSA: prostate-specific antigen; RECIST: Response Evaluation Criteria in Solid Tumors; PCWG3: Prostate Cancer Working Group 3

End point type	Secondary

End point timeframe:

Part A: up to 1340 days; Part A.1: up to 597 days; Part B: 1361 days

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled	Part A - 40mg BID MTD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[53]	1	0[54]	0[55]
Units: Percentage				
number (confidence interval 95%)	(to)	0 (0 to 97.5)	(to)	(to)

Notes:

[53] - No evaluable subject

[54] - No evaluable subject

[55] - No evaluable subject

End point values	Part A - 40mg BID Non-MTD	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	2	0[56]
Units: Percentage				

number (confidence interval 95%)	50.0 (6.8 to 93.2)	0 (0 to 97.5)	50.0 (1.3 to 98.7)	(to)

Notes:

[56] - No evaluable subject

End point values	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	1
Units: Percentage				
number (confidence interval 95%)	0 (0 to 84.2)	0 (0 to 97.5)	100.0 (2.5 to 100.0)	0 (0 to 97.5)

End point values	Part B - Prostate	Part B - Colorectal	Part B - Gynecological	Part B - Breast
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	0[57]	0[58]	0[59]
Units: Percentage				
number (confidence interval 95%)	22.2 (6.4 to 47.6)	(to)	(to)	(to)

Notes:

[57] - No evaluable subject

[58] - No evaluable subject

[59] - No evaluable subject

End point values	Part B - ATM loss			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Percentage				
number (confidence interval 95%)	60.0 (26.2 to 87.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Disease control rate (DCR) of lymphoma responses consistent with Lugano Classification

End point title	Disease control rate (DCR) of lymphoma responses consistent with Lugano Classification

End point description:

DCR was defined as the percentage of subjects with complete response (CR) or partial response (PR) as best overall response, or stable disease (SD) for at least 10 weeks during the course of the study. Best overall responses were to be evaluated by the investigator as per the Lugano Classification (Cheson et al. 2014). EAS was planned to be used for the analysis.

End point type	Secondary

End point timeframe:

0 day as no subject was evaluated as per Lugano Classification

End point values	Part A - 5mg BID	Part A - 10mg BID	Part A - 20mg BID Pooled	Part A - 40mg BID MTD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[60]	0[61]	0[62]	0[63]
Units: Percentage				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[60] - No evaluable subject

[61] - No evaluable subject

[62] - No evaluable subject

[63] - No evaluable subject

End point values	Part A - 40mg BID Non-MTD	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[64]	0[65]	0[66]	0[67]
Units: Percentage				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[64] - No evaluable subject

[65] - No evaluable subject

[66] - No evaluable subject

[67] - No evaluable subject

End point values	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d	Part A.1 - 120mg BID 3d/11d
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[68]	0[69]	0[70]	0[71]
Units: Percentage				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[68] - No evaluable subject

[69] - No evaluable subject

[70] - No evaluable subject

[71] - No evaluable subject

End point values	Part B - Prostate	Part B - Colorectal	Part B - Gynecological	Part B - Breast
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[72]	0[73]	0[74]	0[75]
Units: Percentage				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[72] - No evaluable subject

[73] - No evaluable subject

[74] - No evaluable subject

[75] - No evaluable subject

End point values	Part B - ATM			

	loss			
Subject group type	Reporting group			
Number of subjects analysed	0[76]			
Units: Percentage				
number (confidence interval 95%)	(to)			

Notes:

[76] - No evaluable subject

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

After first administration of study drug up to 30 days after the last dose of study drug. Adverse event reporting for the deaths (all causes) considers all deaths that occurred at any time during the study before the last contact.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Part A - 5mg BID

Reporting group description:

Subjects received elimusertib 5 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Reporting group title	Part A - 10mg BID

Reporting group description:

Description: Subjects received elimusertib 10 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Reporting group title	Part B - Gynecological

Reporting group description:

Description: Subjects with gynecological cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part A - 20mg BID Pooled

Reporting group description:

Description: Subjects received elimusertib 20 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Reporting group title	Part A - 40mg BID MTD

Reporting group description:

Description: Subjects received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Reporting group title	Part A - 40mg BID non MTD

Reporting group description:

Description: Subjects, who were not included in the maximum tolerated dose (MTD) analysis, received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Reporting group title	Part A - 60mg BID

Reporting group description:

Description: Subjects received elimusertib 60 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Reporting group title	Part A - 60mg BID 2w/1w

Reporting group description:

Description: Subjects received elimusertib 60 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with 2 weeks on/1 week off in Part A of the study.

Reporting group title	Part A - 80mg BID

Reporting group description:

Description: Subjects received elimusertib 80 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part A of the study.

Reporting group title	Part A.1 - 60mg BID 3d/11d

Reporting group description:

Description: Subjects received elimusertib 60 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.

Reporting group title	Part A.1 - 80mg BID 3d/11d

Reporting group description:

Description: Subjects received elimusertib 80 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.

Reporting group title	Part A.1 - 100mg BID 3d/11d

Reporting group description:

Description: Subjects received elimusertib 100 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.

Reporting group title	Part A.1 - 120mg BID 3d/11d

Reporting group description:

Description: Subjects received elimusertib 120 mg BID in a 3 days on/11 days off schedule in a 28-day cycle with no break between cycles in Part A.1 of the study.

Reporting group title	Part B - Prostate

Reporting group description:

Description: Subjects with prostate cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - Colorectal

Reporting group description:

Description: Subjects with colorectal cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - Breast

Reporting group description:

Description: Subjects with breast cancer received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Reporting group title	Part B - ATM loss

Reporting group description:

Description: Subjects with ATM loss regardless of cancer type received elimusertib 40 mg BID for 3 days on/4 days off in a weekly schedule in a 21-day cycle with no break between cycles in Part B of the study.

Serious adverse events	Part A - 5mg BID	Part A - 10mg BID	Part B - Gynecological
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	21 / 45 (46.67%)
number of deaths (all causes)	0	0	20
number of deaths resulting from adverse events	0	0	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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			

Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
General physical health deterioration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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			
Liver function test abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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			
Humerus fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medication error			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 45 (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
Subdural haematoma			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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			
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 / 1 (0.00%)	0 / 2 (0.00%)	5 / 45 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
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			
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	5 / 45 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Duodenitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small intestinal obstruction			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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			
Renal impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 45 (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
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
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 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
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	Part A - 20mg BID Pooled	Part A - 40mg BID MTD	Part A - 40mg BID non MTD
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	7 / 24 (29.17%)
number of deaths (all causes)	1	0	4
number of deaths resulting from adverse events	0	0	1

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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			
Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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			
Liver function test abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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			
Humerus fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Femur fracture			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (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
Medication error			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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			
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spinal cord compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (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 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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			
Ascites			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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 pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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 distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
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			
Renal impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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 pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
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	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 8 (62.50%)	2 / 4 (50.00%)	2 / 3 (66.67%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (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
Jugular vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Cough			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			

Liver function test abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Humerus fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medication error			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Hypoaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (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
Syncope			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 distension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (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
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (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
Hypertransaminasaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Renal impairment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (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
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (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
Sinusitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related bacteraemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (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

Serious adverse events	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	4 / 11 (36.36%)	3 / 6 (50.00%)
number of deaths (all causes)	4	9	3
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	1 / 6 (16.67%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Liver function test abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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			
Humerus fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medication error			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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			
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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			
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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			

Renal impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Enterococcal bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (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
Peritonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (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
Groin abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (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
Device related bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
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	Part A.1 - 120mg	Part B - Prostate	Part B - Colorectal

	BID 3d/11d		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 9 (55.56%)	4 / 19 (21.05%)	14 / 24 (58.33%)
number of deaths (all causes)	5	1	8
number of deaths resulting from adverse events	1	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	3 / 24 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Pyrexia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 19 (5.26%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (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
Wheezing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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			
Liver function test abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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			
Humerus fracture			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medication error			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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			
Hypoaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (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
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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 / 9 (11.11%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	2 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (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
Eye disorders			

Vision blurred			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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			
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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 pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (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
Diarrhoea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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			
Renal impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	3 / 24 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (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
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
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	Part B - Breast	Part B - ATM loss	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 19 (26.32%)	14 / 36 (38.89%)	
number of deaths (all causes)	7	17	
number of deaths resulting from adverse events	1	3	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Jugular vein thrombosis			

subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pyrexia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Dyspnoea			
subjects affected / exposed	1 / 19 (5.26%)	2 / 36 (5.56%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			

subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Liver function test abnormal			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medication error			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac disorders			
Bradycardia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac failure			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Hypoaesthesia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Neutropenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Constipation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Small intestinal obstruction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			

subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Herpes zoster			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal bacteraemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			

subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			

subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related bacteraemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoalbuminaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part A - 5mg BID	Part A - 10mg BID	Part B - Gynecological
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	2 / 2 (100.00%)	45 / 45 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0

Skin papilloma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	1 / 45 (2.22%)
occurrences (all)	0	1	1
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1

Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences (all)	0	0	3
Fatigue			
subjects affected / exposed	1 / 1 (100.00%)	1 / 2 (50.00%)	30 / 45 (66.67%)
occurrences (all)	1	1	96
Injection site pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences (all)	0	0	3
Gait disturbance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	3
Swelling face			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	13 / 45 (28.89%)
occurrences (all)	0	0	19

Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	5 / 45 (11.11%)
occurrences (all)	0	0	7
Performance status decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	1 / 45 (2.22%)
occurrences (all)	0	1	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	3
Breast pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pelvic fluid collection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	8 / 45 (17.78%)
occurrences (all)	0	0	11
Dyspnoea			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	13 / 45 (28.89%)
occurrences (all)	1	0	20

Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Laryngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Productive cough			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Laryngeal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1

Rhinitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	4 / 45 (8.89%)
occurrences (all)	0	0	5
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Irritability			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	3
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	3
Ammonia increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	3
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	14 / 45 (31.11%)
occurrences (all)	0	0	86
Haemoglobin decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	4 / 45 (8.89%)
occurrences (all)	0	0	35
Reticulocyte count decreased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	2
White blood cell count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	14 / 45 (31.11%)
occurrences (all)	0	0	83
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	6 / 45 (13.33%)
occurrences (all)	0	0	8
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Contusion			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Ventricular arrhythmia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	6 / 45 (13.33%)
occurrences (all)	0	1	8
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	5 / 45 (11.11%)
occurrences (all)	0	0	5
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	8 / 45 (17.78%)
occurrences (all)	0	0	8
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	1 / 45 (2.22%)
occurrences (all)	0	1	1
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Hemianaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	45 / 45 (100.00%)
occurrences (all)	0	4	450
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	2
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	19 / 45 (42.22%)
occurrences (all)	0	0	116
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	15 / 45 (33.33%)
occurrences (all)	0	0	52
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	3
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Deafness neurosensory			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	6 / 45 (13.33%)
occurrences (all)	0	0	9
Abdominal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	13 / 45 (28.89%)
occurrences (all)	0	0	26
Abdominal pain lower			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences (all)	0	0	3
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	5
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	15 / 45 (33.33%)
occurrences (all)	0	0	27
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	3
Breath odour			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	16 / 45 (35.56%)
occurrences (all)	0	0	36
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	3

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences (all)	0	0	5
Gastric ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	1	0	1
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	26 / 45 (57.78%)
occurrences (all)	0	1	78
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	5 / 45 (11.11%)
occurrences (all)	0	0	5
Pancreatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	20 / 45 (44.44%)
occurrences (all)	0	0	36

Rectal spasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Enterovesical fistula			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Cholecystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	2
Erythema multiforme			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences (all)	0	0	4
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	4
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	4 / 45 (8.89%)
occurrences (all)	0	1	6
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	5 / 45 (11.11%)
occurrences (all)	0	0	14
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences (all)	0	0	4
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Pollakiuria			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	3
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	9
Micturition urgency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	10 / 45 (22.22%)
occurrences (all)	0	0	18
Arthralgia			
subjects affected / exposed	1 / 1 (100.00%)	1 / 2 (50.00%)	2 / 45 (4.44%)
occurrences (all)	1	2	2
Muscular weakness			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	5 / 45 (11.11%)
occurrences (all)	0	0	5
Joint swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Bone pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences (all)	0	0	4
Sacral pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Osteoporosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 45 (6.67%)
occurrences (all)	0	0	3
Musculoskeletal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	4
Osteonecrosis of jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Infections and infestations			
Carbuncle			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0

Peritonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Tooth abscess			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	8 / 45 (17.78%)
occurrences (all)	0	0	11
Vaginal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	4 / 45 (8.89%)
occurrences (all)	0	0	7
Biliary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Medical device site infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	3
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	12
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	15 / 45 (33.33%)
occurrences (all)	0	1	38
Hypomagnesaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	10 / 45 (22.22%)
occurrences (all)	0	0	18
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	16 / 45 (35.56%)
occurrences (all)	0	0	27
Appetite disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Zinc deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Iron overload			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A - 20mg BID Pooled	Part A - 40mg BID MTD	Part A - 40mg BID non MTD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	6 / 6 (100.00%)	24 / 24 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	4
Lymphoedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Fatigue			

subjects affected / exposed	1 / 6 (16.67%)	4 / 6 (66.67%)	10 / 24 (41.67%)
occurrences (all)	3	18	29
Injection site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Swelling face			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	5 / 24 (20.83%)
occurrences (all)	1	1	6
Oedema peripheral			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Performance status decreased			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pelvic fluid collection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	3 / 24 (12.50%)
occurrences (all)	0	2	3
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	3 / 24 (12.50%)
occurrences (all)	0	0	4
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hiccups			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Laryngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Productive cough			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Irritability			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 24 (4.17%)
occurrences (all)	2	1	1
Blood bilirubin increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	2 / 24 (8.33%)
occurrences (all)	2	1	2
Ammonia increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	3 / 24 (12.50%)
occurrences (all)	1	8	27
Haemoglobin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	5	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	0 / 24 (0.00%)
occurrences (all)	4	5	0
Reticulocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Platelet count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	3 / 6 (50.00%)	4 / 6 (66.67%)	1 / 24 (4.17%)
occurrences (all)	9	23	6
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Limb injury			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	2
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Ventricular arrhythmia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	2 / 24 (8.33%)
occurrences (all)	0	1	2
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	4 / 24 (16.67%)
occurrences (all)	0	1	7
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	2 / 24 (8.33%)
occurrences (all)	0	2	2
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hemianaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 6 (83.33%)	6 / 6 (100.00%)	19 / 24 (79.17%)
occurrences (all)	43	100	120
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	1 / 24 (4.17%)
occurrences (all)	0	3	1

Neutropenia			
subjects affected / exposed	2 / 6 (33.33%)	4 / 6 (66.67%)	11 / 24 (45.83%)
occurrences (all)	22	21	38
Thrombocytopenia			
subjects affected / exposed	1 / 6 (16.67%)	4 / 6 (66.67%)	5 / 24 (20.83%)
occurrences (all)	1	6	11
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Deafness neurosensory			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Abdominal discomfort			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	2
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	4 / 24 (16.67%)
occurrences (all)	0	0	5
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	3 / 24 (12.50%)
occurrences (all)	2	1	5
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Breath odour			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	5 / 24 (20.83%)
occurrences (all)	1	2	7
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Gastric ulcer			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 6 (33.33%)	4 / 6 (66.67%)	8 / 24 (33.33%)
occurrences (all)	4	5	21
Stomatitis			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Pancreatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	3 / 6 (50.00%)	2 / 24 (8.33%)
occurrences (all)	1	3	2
Rectal spasm			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Anal incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Enterovesical fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
Cholecystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	2
Rash erythematous			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Plantar erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Proteinuria			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 24 (4.17%)
occurrences (all)	2	1	1
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Muscle spasms			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	3
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Musculoskeletal chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Sacral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Osteoporosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal discomfort			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Osteonecrosis of jaw			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Carbuncle			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	3 / 24 (12.50%)
occurrences (all)	0	1	5
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	3
Biliary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Mucosal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Medical device site infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	2 / 24 (8.33%)
occurrences (all)	2	0	3
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 24 (0.00%)
occurrences (all)	3	2	0
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	5 / 24 (20.83%)
occurrences (all)	2	2	11
Appetite disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Zinc deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Iron overload			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1

Non-serious adverse events	Part A - 60mg BID	Part A - 60mg BID 2w/1w	Part A - 80mg BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	4 / 4 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin papilloma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 8 (50.00%)	3 / 4 (75.00%)	3 / 3 (100.00%)
occurrences (all)	21	4	7
Injection site pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gait disturbance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Swelling face			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	2 / 3 (66.67%)
occurrences (all)	0	2	3
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Performance status decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Breast pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic fluid collection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	2
Dyspnoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laryngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 8 (25.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	2
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Irritability			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Amylase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	11
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ammonia increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	2 / 8 (25.00%)	1 / 4 (25.00%)	2 / 3 (66.67%)
occurrences (all)	4	4	15
Haemoglobin decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	6
Lymphocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reticulocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			

subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	3 / 3 (100.00%)
occurrences (all)	3	0	15
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 8 (25.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hemiparesis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Sciatica			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hemianaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 8 (100.00%)	3 / 4 (75.00%)	3 / 3 (100.00%)
occurrences (all)	83	20	41
Leukocytosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	6 / 8 (75.00%)	2 / 4 (50.00%)	2 / 3 (66.67%)
occurrences (all)	35	17	38

Thrombocytopenia			
subjects affected / exposed	6 / 8 (75.00%)	2 / 4 (50.00%)	2 / 3 (66.67%)
occurrences (all)	16	7	10
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Deafness neurosensory			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	2 / 8 (25.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 8 (25.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	3	2	0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Breath odour			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	1
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Gastric ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	4 / 8 (50.00%)	2 / 4 (50.00%)	1 / 3 (33.33%)
occurrences (all)	6	2	2
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	4
Pancreatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	2
Rectal spasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Enterovesical fistula			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cholecystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	2
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			

subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Renal failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 8 (12.50%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	3	4	0
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Osteoporosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Carbuncle			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Otitis externa			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Biliary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical device site infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hypocalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	2 / 8 (25.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Hypomagnesaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hyponatraemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Hypophosphataemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 8 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Appetite disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Zinc deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron overload			
subjects affected / exposed	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Part A.1 - 60mg BID 3d/11d	Part A.1 - 80mg BID 3d/11d	Part A.1 - 100mg BID 3d/11d
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	10 / 11 (90.91%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vena cava thrombosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 6 (16.67%)	5 / 11 (45.45%)	2 / 6 (33.33%)
occurrences (all)	2	6	2
Injection site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Generalised oedema			

subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Swelling face			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	1 / 6 (16.67%)
occurrences (all)	0	5	1
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Performance status decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic fluid collection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 6 (33.33%)	3 / 11 (27.27%)	1 / 6 (16.67%)
occurrences (all)	3	4	1
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	3 / 11 (27.27%)	1 / 6 (16.67%)
occurrences (all)	0	4	2
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Hiccups			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Laryngeal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	1 / 6 (16.67%)
occurrences (all)	0	8	1
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	1 / 6 (16.67%)
occurrences (all)	0	4	1
Ammonia increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood creatine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood parathyroid hormone increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	1 / 6 (16.67%)	3 / 11 (27.27%)	5 / 6 (83.33%)
occurrences (all)	1	7	26
Haemoglobin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	4 / 6 (66.67%)
occurrences (all)	0	0	31
Reticulocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	18	0
Serum ferritin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	0 / 6 (0.00%)
occurrences (all)	0	11	0
Platelet count increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
White blood cell count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	2 / 6 (33.33%)	3 / 11 (27.27%)	5 / 6 (83.33%)
occurrences (all)	4	9	58
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Fracture			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			

subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Dysgeusia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Dizziness			
subjects affected / exposed	1 / 6 (16.67%)	3 / 11 (27.27%)	0 / 6 (0.00%)
occurrences (all)	1	3	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hemianaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 6 (66.67%)	8 / 11 (72.73%)	6 / 6 (100.00%)
occurrences (all)	12	50	27
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 6 (16.67%)	3 / 11 (27.27%)	1 / 6 (16.67%)
occurrences (all)	1	8	1
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	5 / 11 (45.45%)	1 / 6 (16.67%)
occurrences (all)	0	27	5
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Deafness neurosensory			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 6 (16.67%)	3 / 11 (27.27%)	0 / 6 (0.00%)
occurrences (all)	2	6	0
Abdominal pain lower			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 6 (16.67%)	1 / 11 (9.09%)	1 / 6 (16.67%)
occurrences (all)	8	1	1
Constipation			
subjects affected / exposed	2 / 6 (33.33%)	1 / 11 (9.09%)	2 / 6 (33.33%)
occurrences (all)	2	2	2
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breath odour			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	5 / 11 (45.45%)	1 / 6 (16.67%)
occurrences (all)	1	5	5
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			

subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Glossodynia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	5 / 6 (83.33%)	6 / 11 (54.55%)	2 / 6 (33.33%)
occurrences (all)	9	10	3
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	3 / 11 (27.27%)	2 / 6 (33.33%)
occurrences (all)	6	3	2
Rectal spasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Enterovesical fistula			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Cholecystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Erythema multiforme			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	1 / 6 (16.67%)
occurrences (all)	0	1	2
Micturition urgency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 11 (9.09%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 11 (27.27%)	0 / 6 (0.00%)
occurrences (all)	0	5	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Osteoporosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Carbuncle			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Fungal skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Diverticulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Peritonitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	2 / 11 (18.18%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Vaginal infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Biliary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Medical device site infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 6 (16.67%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Hypercalcaemia			

subjects affected / exposed	2 / 6 (33.33%)	2 / 11 (18.18%)	0 / 6 (0.00%)
occurrences (all)	4	3	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	0 / 6 (0.00%)
occurrences (all)	0	5	0
Hypermagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Hypomagnesaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	1 / 6 (16.67%)	3 / 11 (27.27%)	0 / 6 (0.00%)
occurrences (all)	2	6	0
Decreased appetite			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	3 / 6 (50.00%)
occurrences (all)	0	2	5
Appetite disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Zinc deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Iron overload			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A.1 - 120mg BID 3d/11d	Part B - Prostate	Part B - Colorectal
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	19 / 19 (100.00%)	23 / 24 (95.83%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Skin papilloma			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	1 / 24 (4.17%)
occurrences (all)	0	5	1
Lymphoedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hypotension			

subjects affected / exposed	1 / 9 (11.11%)	2 / 19 (10.53%)	2 / 24 (8.33%)
occurrences (all)	1	2	2
Embolism			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	3 / 9 (33.33%)	4 / 19 (21.05%)	12 / 24 (50.00%)
occurrences (all)	4	6	25
Injection site pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 9 (11.11%)	2 / 19 (10.53%)	1 / 24 (4.17%)
occurrences (all)	1	2	1
Gait disturbance			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Malaise			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Swelling face			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 9 (33.33%)	0 / 19 (0.00%)	4 / 24 (16.67%)
occurrences (all)	11	0	6
Oedema peripheral			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	4 / 24 (16.67%)
occurrences (all)	1	0	6
Performance status decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pelvic fluid collection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	2
Dyspnoea			
subjects affected / exposed	1 / 9 (11.11%)	2 / 19 (10.53%)	6 / 24 (25.00%)
occurrences (all)	1	3	7
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Hiccups			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Laryngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	2 / 24 (8.33%)
occurrences (all)	0	1	2

Irritability			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	4 / 24 (16.67%)
occurrences (all)	1	0	7
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	2 / 24 (8.33%)
occurrences (all)	0	1	6
Amylase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	1 / 24 (4.17%)
occurrences (all)	0	2	7
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	4 / 24 (16.67%)
occurrences (all)	1	0	7
Ammonia increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Electrocardiogram QT prolonged			
subjects affected / exposed	2 / 9 (22.22%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
Neutrophil count decreased			
subjects affected / exposed	4 / 9 (44.44%)	2 / 19 (10.53%)	6 / 24 (25.00%)
occurrences (all)	15	7	25
Haemoglobin decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	3 / 24 (12.50%)
occurrences (all)	0	0	13
International normalised ratio increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 9 (0.00%)	2 / 19 (10.53%)	1 / 24 (4.17%)
occurrences (all)	0	3	9
Lymphocyte count decreased			
subjects affected / exposed	3 / 9 (33.33%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences (all)	13	0	4
Reticulocyte count decreased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Serum ferritin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
Platelet count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	2
White blood cell count decreased			

subjects affected / exposed	4 / 9 (44.44%)	2 / 19 (10.53%)	7 / 24 (29.17%)
occurrences (all)	31	10	34
Weight decreased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Fracture			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Tachycardia			

subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 9 (22.22%)	2 / 19 (10.53%)	1 / 24 (4.17%)
occurrences (all)	2	2	1
Dysgeusia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	2 / 24 (8.33%)
occurrences (all)	0	1	2
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Sciatica			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hemianaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 9 (66.67%)	17 / 19 (89.47%)	19 / 24 (79.17%)
occurrences (all)	35	87	135
Leukocytosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	5	0
Neutropenia			
subjects affected / exposed	1 / 9 (11.11%)	7 / 19 (36.84%)	8 / 24 (33.33%)
occurrences (all)	26	28	46
Thrombocytopenia			
subjects affected / exposed	5 / 9 (55.56%)	3 / 19 (15.79%)	7 / 24 (29.17%)
occurrences (all)	33	12	25
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Deafness neurosensory			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Photopsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 9 (11.11%)	1 / 19 (5.26%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
Abdominal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	3 / 24 (12.50%)
occurrences (all)	1	0	4
Abdominal pain lower			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Constipation			

subjects affected / exposed	2 / 9 (22.22%)	3 / 19 (15.79%)	4 / 24 (16.67%)
occurrences (all)	3	4	4
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Breath odour			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 9 (0.00%)	2 / 19 (10.53%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Gastric ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 9 (33.33%)	2 / 19 (10.53%)	8 / 24 (33.33%)
occurrences (all)	7	2	11
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Pancreatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	4 / 9 (44.44%)	2 / 19 (10.53%)	5 / 24 (20.83%)
occurrences (all)	7	2	5
Rectal spasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Enterovesical fistula			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Hepatic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cholecystitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Erythema multiforme			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	4 / 24 (16.67%)
occurrences (all)	0	0	5
Pruritus			

subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Rash erythematous			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Plantar erythema			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Micturition urgency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0

Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Arthralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Sacral pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	2 / 19 (10.53%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Osteoporosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Spinal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Carbuncle			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Diverticulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Pelvic infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	2 / 19 (10.53%)	1 / 24 (4.17%)
occurrences (all)	0	2	2
Vaginal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	4 / 24 (16.67%)
occurrences (all)	0	1	5
Biliary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Medical device site infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 9 (22.22%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences (all)	2	0	2
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	3 / 9 (33.33%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	12	0	0
Hyperkalaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	3	0
Hyperuricaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	4
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	2 / 9 (22.22%)	1 / 19 (5.26%)	2 / 24 (8.33%)
occurrences (all)	7	1	4
Decreased appetite			
subjects affected / exposed	4 / 9 (44.44%)	3 / 19 (15.79%)	8 / 24 (33.33%)
occurrences (all)	7	4	8
Appetite disorder			
subjects affected / exposed	1 / 9 (11.11%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Zinc deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			

subjects affected / exposed	0 / 9 (0.00%)	1 / 19 (5.26%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Iron overload			
subjects affected / exposed	0 / 9 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B - Breast	Part B - ATM loss	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 19 (100.00%)	35 / 36 (97.22%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Skin papilloma			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 19 (5.26%)	4 / 36 (11.11%)	
occurrences (all)	2	12	
Lymphoedema			
subjects affected / exposed	1 / 19 (5.26%)	1 / 36 (2.78%)	
occurrences (all)	1	2	
Vena cava thrombosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Hypotension			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Embolism			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			

Tooth extraction			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Asthenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Chills			
subjects affected / exposed	2 / 19 (10.53%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Fatigue			
subjects affected / exposed	3 / 19 (15.79%)	14 / 36 (38.89%)	
occurrences (all)	4	21	
Injection site pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Generalised oedema			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Gait disturbance			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Malaise			

subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Mucosal inflammation			
subjects affected / exposed	1 / 19 (5.26%)	2 / 36 (5.56%)	
occurrences (all)	1	2	
Swelling face			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Pain			
subjects affected / exposed	1 / 19 (5.26%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Pyrexia			
subjects affected / exposed	2 / 19 (10.53%)	4 / 36 (11.11%)	
occurrences (all)	4	4	
Oedema peripheral			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Performance status decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Peripheral swelling			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Breast pain			

subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Erectile dysfunction			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Pelvic fluid collection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 19 (26.32%)	3 / 36 (8.33%)	
occurrences (all)	5	3	
Dyspnoea			
subjects affected / exposed	3 / 19 (15.79%)	9 / 36 (25.00%)	
occurrences (all)	4	12	
Epistaxis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Hiccups			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hypoxia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Laryngeal pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Pleural effusion			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	3	
Productive cough			

subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Pneumonitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Pleuritic pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Pulmonary embolism			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Laryngeal inflammation			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Rhinorrhoea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Depression			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Irritability			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 19 (15.79%)	4 / 36 (11.11%)	
occurrences (all)	5	16	
Blood bilirubin increased			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	3	
Amylase increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	3	0	
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 19 (26.32%)	5 / 36 (13.89%)	
occurrences (all)	7	12	
Ammonia increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Blood creatine increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	4	
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

Neutrophil count decreased				
subjects affected / exposed	2 / 19 (10.53%)	6 / 36 (16.67%)		
occurrences (all)	39	32		
Haemoglobin decreased				
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
International normalised ratio increased				
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)		
occurrences (all)	0	6		
Lipase increased				
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
Lymphocyte count decreased				
subjects affected / exposed	1 / 19 (5.26%)	1 / 36 (2.78%)		
occurrences (all)	16	9		
Reticulocyte count decreased				
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
Serum ferritin increased				
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)		
occurrences (all)	0	1		
Blood alkaline phosphatase increased				
subjects affected / exposed	0 / 19 (0.00%)	3 / 36 (8.33%)		
occurrences (all)	0	7		
Platelet count increased				
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
White blood cell count increased				
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
White blood cell count decreased				
subjects affected / exposed	2 / 19 (10.53%)	9 / 36 (25.00%)		
occurrences (all)	26	39		
Weight decreased				

subjects affected / exposed	0 / 19 (0.00%)	4 / 36 (11.11%)	
occurrences (all)	0	5	
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Limb injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Atrial fibrillation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Ventricular arrhythmia			

subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Left ventricular dysfunction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 19 (10.53%)	4 / 36 (11.11%)	
occurrences (all)	3	4	
Dysgeusia			
subjects affected / exposed	1 / 19 (5.26%)	2 / 36 (5.56%)	
occurrences (all)	1	2	
Dizziness			
subjects affected / exposed	1 / 19 (5.26%)	4 / 36 (11.11%)	
occurrences (all)	1	5	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Presyncope			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	1 / 19 (5.26%)	1 / 36 (2.78%)	
occurrences (all)	1	2	
Neuralgia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Lethargy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hemiparesis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Sciatica			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

Hemianaesthesia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	14 / 19 (73.68%)	31 / 36 (86.11%)	
occurrences (all)	135	236	
Leukocytosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Febrile neutropenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 19 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	19	
Lymphopenia			
subjects affected / exposed	1 / 19 (5.26%)	2 / 36 (5.56%)	
occurrences (all)	1	10	
Neutropenia			
subjects affected / exposed	14 / 19 (73.68%)	13 / 36 (36.11%)	
occurrences (all)	92	81	
Thrombocytopenia			
subjects affected / exposed	7 / 19 (36.84%)	10 / 36 (27.78%)	
occurrences (all)	33	51	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Ear pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Tinnitus			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Deafness neurosensory			

subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Vision blurred			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Vitreous floaters			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Photopsia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Abdominal discomfort			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Abdominal pain			
subjects affected / exposed	5 / 19 (26.32%)	5 / 36 (13.89%)	
occurrences (all)	6	6	
Abdominal pain lower			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	3 / 19 (15.79%)	11 / 36 (30.56%)	
occurrences (all)	6	11	
Ascites			

subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	3	
Breath odour			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Abdominal tenderness			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	2 / 19 (10.53%)	7 / 36 (19.44%)	
occurrences (all)	3	10	
Dry mouth			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Dyspepsia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 19 (5.26%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Gastric ulcer			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	2	
Dysphagia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	3	
Glossodynia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Mouth ulceration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Nausea			

subjects affected / exposed	6 / 19 (31.58%)	12 / 36 (33.33%)	
occurrences (all)	13	16	
Stomatitis			
subjects affected / exposed	2 / 19 (10.53%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Pancreatitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Proctalgia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Oesophagitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	2 / 19 (10.53%)	9 / 36 (25.00%)	
occurrences (all)	6	10	
Rectal spasm			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Paraesthesia oral			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Anal incontinence			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Enterovesical fistula			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Hepatic pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

Hyperbilirubinaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Cholecystitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Dermatitis acneiform			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	2 / 19 (10.53%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Erythema multiforme			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Night sweats			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	2 / 19 (10.53%)	1 / 36 (2.78%)	
occurrences (all)	3	1	
Pruritus			
subjects affected / exposed	2 / 19 (10.53%)	1 / 36 (2.78%)	
occurrences (all)	2	2	
Rash erythematous			

subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Plantar erythema			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	1 / 19 (5.26%)	2 / 36 (5.56%)	
occurrences (all)	1	3	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Haematuria			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	2	
Pollakiuria			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Proteinuria			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Micturition urgency			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Renal failure			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Urinary incontinence			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Urinary retention			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Acute kidney injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hypothyroidism			
subjects affected / exposed	2 / 19 (10.53%)	1 / 36 (2.78%)	
occurrences (all)	2	4	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 19 (10.53%)	10 / 36 (27.78%)	
occurrences (all)	3	11	
Arthralgia			
subjects affected / exposed	1 / 19 (5.26%)	2 / 36 (5.56%)	
occurrences (all)	1	2	
Muscular weakness			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Muscle spasms			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Joint swelling			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Groin pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Flank pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Bone pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Sacral pain			

subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	1 / 19 (5.26%)	3 / 36 (8.33%)	
occurrences (all)	2	4	
Osteoporosis			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Neck pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal discomfort			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	1 / 19 (5.26%)	2 / 36 (5.56%)	
occurrences (all)	1	2	
Osteonecrosis of jaw			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Spinal pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Carbuncle			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Diverticulitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	2	0	

Cellulitis			
subjects affected / exposed	2 / 19 (10.53%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Herpes zoster			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Peritonitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Pharyngitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Otitis externa			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Tooth abscess			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Pelvic infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

Urinary tract infection			
subjects affected / exposed	2 / 19 (10.53%)	5 / 36 (13.89%)	
occurrences (all)	2	5	
Vaginal infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 19 (5.26%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Biliary tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Mucosal infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	2 / 19 (10.53%)	0 / 36 (0.00%)	
occurrences (all)	3	0	
Medical device site infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hypercalcaemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Hyperglycaemia			
subjects affected / exposed	0 / 19 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	5	
Hyperkalaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hypermagnesaemia			

subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hyperuricaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Hypoalbuminaemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	4	
Hypocalcaemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	5	
Hypokalaemia			
subjects affected / exposed	0 / 19 (0.00%)	8 / 36 (22.22%)	
occurrences (all)	0	10	
Hypomagnesaemia			
subjects affected / exposed	1 / 19 (5.26%)	2 / 36 (5.56%)	
occurrences (all)	1	6	
Hyponatraemia			
subjects affected / exposed	1 / 19 (5.26%)	3 / 36 (8.33%)	
occurrences (all)	1	13	
Hypophosphataemia			
subjects affected / exposed	0 / 19 (0.00%)	6 / 36 (16.67%)	
occurrences (all)	0	16	
Decreased appetite			
subjects affected / exposed	3 / 19 (15.79%)	7 / 36 (19.44%)	
occurrences (all)	5	10	
Appetite disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Zinc deficiency			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Vitamin D deficiency			
subjects affected / exposed	1 / 19 (5.26%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Iron overload			

subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 36 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 June 2017	Protocol Amendment 2 introduced the following changes: • An additional Part C was added, which included the combination therapy of elimusertib with radium-223 dichloride in patients with advanced/refractory metastatic CRPC.
24 July 2017	Protocol Amendment 3 introduced the following changes: • Inclusion criterion regarding patients with tumors resistant or refractory to standard treatment and in whom, in the opinion of the investigator, experimental treatment with elimusertib could be of benefit, was modified to further specify that the patients would not benefit from standard therapy, as per request from the FDA.
16 November 2017	Protocol Amendment 3 introduced the following changes: • An additional Japanese patient subgroup (J-arm) in Part A was added, which included the single agent of elimusertib in Japanese patients with advanced/refractory solid tumors. • The description of the test drug for Part C of the study, radium-223 dichloride, was changed to Xofigo.
03 July 2018	Protocol Amendment 6 introduced the following changes: • Study Part C, combination therapy of the study intervention elimusertib with Xofigo, was removed from the protocol because the potential for overlapping bone toxicity for the combination of elimusertib and Xofigo could not be excluded. • The cancer types eligible for Part B of the study were revised: 1) the ATM loss indication agnostic cohort was added and replaced the MCL cohort; 2) in addition the HER2-negative breast cancer replaced the lung cancer cohort. • Option for an alternative schedule (i.e., 1-week break) in the expansion added. • The mandatory time frame for patients and female partners of childbearing potential from male study patients to use contraception after last dose of study intervention was changed from 4 to 6 months (as described per local Amendment 5 for Japan). • Inclusion and exclusion criteria, DLT definition for J-arm of Part A, and starting dose of J-arm of Part A updated to incorporate changes from local Amendment 5 for Japan.
26 March 2019	Protocol Amendment 7 introduced the following changes: • Assessment of effect of food on the PK of elimusertib added. An exploratory dosing schedule was added for a starting dose of 60 mg (up to a maximum potential tested dose of 80 mg) of elimusertib given in a 3 days on/ 11 days off, 28-day cycle with the goal of optimizing the benefit-risk profile for patients. • MCL and DLBCL replaced with NHL. • Long-term follow-up period added to study design to collect survival data. • Inclusion criterion for patients with measurable disease clarified per external guidance (Lugano and PCWG3): only non-prostate cancer patients with measurable (ie, target) lesion(s) could be enrolled while prostate cancer patients with only non-target lesion(s) could still be enrolled. • Inclusion criterion for patients with adequate bone marrow function revised to indicate that values listed are to be independent of RBC transfusions or G-CSF. The acceptable hemoglobin value changed from ≥8.5 g/dL to ≥9 g/dL. • Hematological criteria for DLT adapted. • Guidance on hematological and non-hematological toxicities for dose modification guidelines revised.
05 June 2020	Protocol Amendment 9 introduced the following changes: • For Part A.1, maximum potential tested dose revised to allow doses higher than 80 mg BID to be explored.

19 May 2022	Protocol Amendment 10 introduced the following changes: • Part B.1 added to study to evaluate patients with MCL. • Exploratory objective added to evaluate safety, PK, and antitumor activity of elimusertib in patients with relapsed or refractor MCL. • Primary completion definition updated to indicate that primary completion for the purpose of final collection of data for the primary outcome is defined as the date of the last visit of the last patient in Part A, Part A.1 and Part B, or 18 months after the last patient first treatment visit (whichever comes first), or the last patient withdraws consent to further follow-up, or dies, whichever occurred first. • Inclusion criteria updated to specify which parts of the study the criteria should be applied to.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Elimusertib was tested up to 120mg BID on 3 days on/11 days off schedule, but MTD/RP2D was not established for this dosing schedule. One screen failure subject without birth date was counted in 18-64 group in table "Subjects enrolled per age group".

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32988960