Clinical trial results:
A Phase II, multi-center, open label study of NIR178 in combination with PDR001 in patients with selected advanced solid tumors and non-Hodgkin lymphoma

Summary

EudraCT number	2017-000241-49
Trial protocol	DE BE CZ AT ES NL FR IT
Global end of trial date	14 February 2023

Results information

Result version number	v1 (current)
This version publication date	21 February 2024
First version publication date	21 February 2024

Trial information

Trial identification

Sponsor protocol code	CNIR178X2201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03207867
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis campus, Basel, Switzerland, CH-4056
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 February 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 February 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the trial were:
Part 1: To evaluate the efficacy of NIR178 and PDR001 combination in patients with selected advanced solid tumors and diffuse large B cell lymphoma (DLBCL).
Part 2: To assess the efficacy of continuous and several intermittent dosing schedules of NIR178 in combination with PDR001 in non-small cell lung cancer (NSCLC).
Part 3: To evaluate efficacy of intermittent or continuous dosing schedule of NIR178 in one or two selected tumor types.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

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

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 1
Country: Number of subjects enrolled	Australia: 8
Country: Number of subjects enrolled	Austria: 17
Country: Number of subjects enrolled	Belgium: 19
Country: Number of subjects enrolled	Czechia: 26
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	Germany: 24
Country: Number of subjects enrolled	Italy: 26
Country: Number of subjects enrolled	Japan: 9
Country: Number of subjects enrolled	Netherlands: 14
Country: Number of subjects enrolled	Singapore: 23
Country: Number of subjects enrolled	Spain: 21
Country: Number of subjects enrolled	Switzerland: 29
Country: Number of subjects enrolled	Taiwan: 53
Country: Number of subjects enrolled	United States: 36

Worldwide total number of subjects	315
EEA total number of subjects	156

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)	199
From 65 to 84 years	115
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants took part in 21 investigative sites in 15 countries.

Pre-assignment

Screening details:

The screening period began once patients had signed the study informed consent. Screening evaluations had to be completed within 21 days prior to the first dose of treatment except for the radiological tumor assessment which had to be performed within 28 days prior to the first dose. After screening, the treatment period started on Cycle 1 Day 1.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: RCC naïve 160 mg

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy

Arm type	Experimental
Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered twice daily (BID) continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

PDR001 400 mg was administered via intravenous (i.v.) infusion over 30 minutes once every 4 weeks (Q4W).

Arm title	Part 1: RCC naïve 240 mg

Arm description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 240 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: RCC pre 240 mg

Arm description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 240 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: Pancreatic 160 mg

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer

Arm type	Experimental
Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Arm title	Part 1: Urothelial 160 mg

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer

Arm type	Experimental

Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: H-N naïve 160 mg

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: H-N pre 160 mg

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: H-N pre 240 mg

Arm description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 240 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: MSS CRC wt 160 mg

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: MSS CRC mu 160 mg

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant

Arm type	Experimental

Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: MSS CRC unk 160 mg

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with unknown RAS status

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: TNBC 160 mg

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:	
NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.	

Arm title	Part 1: Melanoma naïve 160 mg
Arm description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had not been previously treated with immuno-oncology therapy	
Arm type	Experimental
Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).	
Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.	
Arm title	Part 1: Melanoma pre 160 mg
Arm description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	
Arm type	Experimental
Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).	
Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.	
Arm title	Part 1: DLBCL 160 mg
Arm description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	
Arm type	Experimental

Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: DLBCL 240 mg

Arm description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 240 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 1: mCRPC 240 mg

Arm description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 240 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 2: NSCLC 160 mg cont

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 2: NSCLC 160 mg 2wk-on/2wk-off

Arm description:

NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID 2 weeks on/2 weeks off. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 2: NSCLC 160 mg 1wk-on/1wk-off

Arm description:

NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)

Arm type	Experimental

Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID 1 week on/1 week off. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	Part 3: TNBC 160 mg cont

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W).

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a film-coated tablet (FCT) within 60 minutes prior to PDR001 infusion.

Arm title	JSR: 80 mg cont

Arm description:

NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in

Arm type	Experimental
Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 80 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W). Treatment with PDR001 was started on Cycle 2 Day 1.

Arm title	JSR: 160 mg cont

Arm description:

NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W). Treatment with PDR001 was started on Cycle 2 Day 1.

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 160 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Arm title	JSR: 240 mg cont

Arm description:

NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in

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

Dosage and administration details:

PDR001 400 mg was administered via i.v. infusion over 30 minutes once every 4 weeks (Q4W). Treatment with PDR001 was started on Cycle 1 Day 1.

Investigational medicinal product name	NIR178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

NIR178 240 mg was administered BID continuously. NIR178 was administered orally as a capsule within 60 minutes prior to PDR001 infusion.

Number of subjects in period 1	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg
Started	11	12	11
Completed	0	0	0
Not completed	11	12	11
Physician decision	3	5	-
Adverse Event	1	-	1
Death	-	-	-
Progressive Disease	7	7	9
Patient/guardian Decision	-	-	1

Number of subjects in period 1	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg
Started	14	14	15
Completed	0	0	0
Not completed	14	14	15
Physician decision	3	2	-
Adverse Event	-	-	2
Death	-	-	1
Progressive Disease	10	11	10
Patient/guardian Decision	1	1	2

Number of subjects in period 1	Part 1: H-N pre 160 mg	Part 1: H-N pre 240 mg	Part 1: MSS CRC wt 160 mg
Started	11	12	27
Completed	0	0	0
Not completed	11	12	27
Physician decision	-	-	4
Adverse Event	1	1	2
Death	-	3	1
Progressive Disease	9	8	19
Patient/guardian Decision	1	-	1

Number of subjects in period 1	Part 1: MSS CRC mu 160 mg	Part 1: MSS CRC unk 160 mg	Part 1: TNBC 160 mg
Started	29	2	30
Completed	0	0	0
Not completed	29	2	30
Physician decision	2	-	4
Adverse Event	2	-	-
Death	2	-	1
Progressive Disease	23	2	24
Patient/guardian Decision	-	-	1

Number of subjects in period 1	Part 1: Melanoma naïve 160 mg	Part 1: Melanoma pre 160 mg	Part 1: DLBCL 160 mg

Started	3	13	13
Completed	0	0	0
Not completed	3	13	13
Physician decision	-	-	2
Adverse Event	-	-	-
Death	-	1	-
Progressive Disease	3	11	9
Patient/guardian Decision	-	1	2

Number of subjects in period 1	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg	Part 2: NSCLC 160 mg cont
Started	6	15	22
Completed	0	0	0
Not completed	6	15	22
Physician decision	1	1	2
Adverse Event	-	3	1
Death	-	-	2
Progressive Disease	5	10	14
Patient/guardian Decision	-	1	3

Number of subjects in period 1	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Started	20	20	6
Completed	0	0	0
Not completed	20	20	6
Physician decision	1	3	-
Adverse Event	2	1	-
Death	-	1	-
Progressive Disease	13	14	6
Patient/guardian Decision	4	1	-

Number of subjects in period 1	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont
Started	3	3	3
Completed	0	0	0
Not completed	3	3	3
Physician decision	-	-	-
Adverse Event	-	-	-
Death	-	-	-
Progressive Disease	3	3	3
Patient/guardian Decision	-	-	-

Reporting groups	
Reporting group title	Part 1: RCC naïve 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	
Reporting group title	Part 1: RCC naïve 240 mg
Reporting group description:	
NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	
Reporting group title	Part 1: RCC pre 240 mg
Reporting group description:	
NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	
Reporting group title	Part 1: Pancreatic 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	
Reporting group title	Part 1: Urothelial 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	
Reporting group title	Part 1: H-N naïve 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	
Reporting group title	Part 1: H-N pre 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	
Reporting group title	Part 1: H-N pre 240 mg
Reporting group description:	
NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	
Reporting group title	Part 1: MSS CRC wt 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	
Reporting group title	Part 1: MSS CRC mu 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	
Reporting group title	Part 1: MSS CRC unk 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with unknown RAS status	
Reporting group title	Part 1: TNBC 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	
Reporting group title	Part 1: Melanoma naïve 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had not been previously treated with immuno-oncology therapy	
Reporting group title	Part 1: Melanoma pre 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy

Reporting group title	Part 1: DLBCL 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)

Reporting group title	Part 1: DLBCL 240 mg

Reporting group description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)

Reporting group title	Part 1: mCRPC 240 mg

Reporting group description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)

Reporting group title	Part 2: NSCLC 160 mg cont

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)

Reporting group title	Part 2: NSCLC 160 mg 2wk-on/2wk-off

Reporting group description:

NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)

Reporting group title	Part 2: NSCLC 160 mg 1wk-on/1wk-off

Reporting group description:

NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)

Reporting group title	Part 3: TNBC 160 mg cont

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)

Reporting group title	JSR: 80 mg cont

Reporting group description:

NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in

Reporting group title	JSR: 160 mg cont

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in

Reporting group title	JSR: 240 mg cont

Reporting group description:

NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in

Reporting group values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg
Number of subjects	11	12	11
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0

Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	6	9
From 65-84 years	6	6	2
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	65.5	60.0	60.6
standard deviation	± 10.86	± 11.96	± 8.54
Sex: Female, Male			
Units: participants			
Female	3	0	2
Male	8	12	9
Race/Ethnicity, Customized			
Units: Subjects			
White	9	3	10
Black or African American	0	0	0
Asian	2	8	0
American Indian or Alaska Native	0	0	0
Other	0	0	0
Unknown	0	1	1

Reporting group values	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg
Number of subjects	14	14	15
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	9	6	10
From 65-84 years	5	8	5
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	60.4	66.9	61.6
standard deviation	± 8.98	± 9.63	± 7.13
Sex: Female, Male			
Units: participants			
Female	6	5	2
Male	8	9	13
Race/Ethnicity, Customized			
Units: Subjects			
White	13	5	14
Black or African American	0	1	0
Asian	0	8	1
American Indian or Alaska Native	0	0	0
Other	0	0	0

Unknown	1	0	0

Reporting group values	Part 1: H-N pre 160 mg	Part 1: H-N pre 240 mg	Part 1: MSS CRC wt 160 mg
Number of subjects	11	12	27
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	7	8	21
From 65-84 years	4	4	6
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	59.4	60.2	56.5
standard deviation	± 9.05	± 7.07	± 9.04
Sex: Female, Male Units: participants			
Female	3	3	9
Male	8	9	18
Race/Ethnicity, Customized Units: Subjects			
White	9	12	20
Black or African American	0	0	0
Asian	0	0	6
American Indian or Alaska Native	1	0	0
Other	0	0	1
Unknown	1	0	0

Reporting group values	Part 1: MSS CRC mu 160 mg	Part 1: MSS CRC unk 160 mg	Part 1: TNBC 160 mg
Number of subjects	29	2	30
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	21	2	26
From 65-84 years	8	0	4
85 years and over	0	0	0

Age Continuous Units: years			
arithmetic mean	58.1	46.0	49.8
standard deviation	± 11.21	± 15.56	± 10.81
Sex: Female, Male Units: participants			
Female	8	1	30
Male	21	1	0
Race/Ethnicity, Customized Units: Subjects			
White	23	2	21
Black or African American	0	0	0
Asian	1	0	2
American Indian or Alaska Native	0	0	0
Other	0	0	0
Unknown	5	0	7

Reporting group values	Part 1: Melanoma naïve 160 mg	Part 1: Melanoma pre 160 mg	Part 1: DLBCL 160 mg
Number of subjects	3	13	13
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	10	8
From 65-84 years	1	3	5
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	50.3	54.2	55.0
standard deviation	± 20.65	± 14.87	± 18.65
Sex: Female, Male Units: participants			
Female	1	3	7
Male	2	10	6
Race/Ethnicity, Customized Units: Subjects			
White	1	13	7
Black or African American	0	0	0
Asian	2	0	4
American Indian or Alaska Native	0	0	0
Other	0	0	0
Unknown	0	0	2

Reporting group values	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg	Part 2: NSCLC 160 mg cont
Number of subjects	6	15	22

Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	4	11
From 65-84 years	3	10	11
85 years and over	0	1	0
Age Continuous Units: years			
arithmetic mean	61.5	68.3	65.0
standard deviation	± 13.10	± 8.14	± 9.02
Sex: Female, Male Units: participants			
Female	3	0	7
Male	3	15	15
Race/Ethnicity, Customized Units: Subjects			
White	0	13	10
Black or African American	0	0	0
Asian	6	2	11
American Indian or Alaska Native	0	0	0
Other	0	0	1
Unknown	0	0	0

Reporting group values	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Number of subjects	20	20	6
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	12	8	4
From 65-84 years	8	12	2
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	61.8	64.2	58.5
standard deviation	± 9.51	± 8.94	± 16.16
Sex: Female, Male Units: participants			
Female	7	8	6

Male	13	12	0

Race/Ethnicity, Customized Units: Subjects			
White	7	7	1
Black or African American	0	0	0
Asian	13	12	0
American Indian or Alaska Native	0	0	0
Other	0	0	3
Unknown	0	1	2

Reporting group values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont
Number of subjects	3	3	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	2	3
From 65-84 years	1	1	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	61.3	57.0	44.3
standard deviation	± 10.69	± 9.54	± 8.33
Sex: Female, Male Units: participants			
Female	3	1	1
Male	0	2	2
Race/Ethnicity, Customized Units: Subjects			
White	0	0	0
Black or African American	3	3	3
Asian	0	0	0
American Indian or Alaska Native	0	0	0
Other	0	0	0
Unknown	0	0	0

Reporting group values	Total		
Number of subjects	315		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		

Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	199		
From 65-84 years	115		
85 years and over	1		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: participants			
Female	119		
Male	196		
Race/Ethnicity, Customized			
Units: Subjects			
White	200		
Black or African American	10		
Asian	78		
American Indian or Alaska Native	1		
Other	5		
Unknown	21		

End points

End points reporting groups

Reporting group title	Part 1: RCC naïve 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	
Reporting group title	Part 1: RCC naïve 240 mg
Reporting group description:	
NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	
Reporting group title	Part 1: RCC pre 240 mg
Reporting group description:	
NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	
Reporting group title	Part 1: Pancreatic 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	
Reporting group title	Part 1: Urothelial 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	
Reporting group title	Part 1: H-N naïve 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	
Reporting group title	Part 1: H-N pre 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	
Reporting group title	Part 1: H-N pre 240 mg
Reporting group description:	
NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	
Reporting group title	Part 1: MSS CRC wt 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	
Reporting group title	Part 1: MSS CRC mu 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	
Reporting group title	Part 1: MSS CRC unk 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with unknown RAS status	
Reporting group title	Part 1: TNBC 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	
Reporting group title	Part 1: Melanoma naïve 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had not been previously treated with immuno-oncology therapy	

Reporting group title	Part 1: Melanoma pre 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	
Reporting group title	Part 1: DLBCL 160 mg
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	
Reporting group title	Part 1: DLBCL 240 mg
Reporting group description:	
NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	
Reporting group title	Part 1: mCRPC 240 mg
Reporting group description:	
NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)	
Reporting group title	Part 2: NSCLC 160 mg cont
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	
Reporting group title	Part 2: NSCLC 160 mg 2wk-on/2wk-off
Reporting group description:	
NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	
Reporting group title	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Reporting group description:	
NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	
Reporting group title	Part 3: TNBC 160 mg cont
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	
Reporting group title	JSR: 80 mg cont
Reporting group description:	
NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	
Reporting group title	JSR: 160 mg cont
Reporting group description:	
NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	
Reporting group title	JSR: 240 mg cont
Reporting group description:	
NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in	
Subject analysis set title	Part 1: RCC naïve + pre 240 mg
Subject analysis set type	Full analysis
Subject analysis set description:	
NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with immuno-oncology therapy	
Subject analysis set title	Part 1: H-N naïve + pre 160 mg
Subject analysis set type	Full analysis
Subject analysis set description:	
NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and pretreated with immuno-oncology therapy	
Subject analysis set title	Part 1: MSS CRC 160 mg
Subject analysis set type	Full analysis

Subject analysis set description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtype, RAS mutant and RAS unknown status

Subject analysis set title	Part 1: Melanoma naïve + pre 160 mg
Subject analysis set type	Full analysis

Subject analysis set description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with immuno-oncology therapy

Subject analysis set title	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)
Subject analysis set type	Full analysis

Subject analysis set description:

Patients in Part 1 and 2 who received NIR178 160 mg as a capsule in combination with PDR001 400 mg every 4 weeks

Subject analysis set title	NIR178 240 mg capsule in Non-Japanese (Part 1)
Subject analysis set type	Full analysis

Subject analysis set description:

Patients in Part 1 who received NIR178 240 mg as a capsule in combination with PDR001 400 mg every 4 weeks

Subject analysis set title	NIR178 160 mg tablet in Non-Japanese (Part 3)
Subject analysis set type	Full analysis

Subject analysis set description:

Patients in Part 3 who received NIR178 160 mg as a film-coated tablet in combination with PDR001 400 mg every 4 weeks

Subject analysis set title	Non-Japanese patients
Subject analysis set type	Full analysis

Subject analysis set description:

Patients in Parts 1, 2 and 3 who received NIR178 (any dose level) in combination with PDR001 400 mg every 4 weeks

Subject analysis set title	Japanese patients
Subject analysis set type	Full analysis

Subject analysis set description:

Patients in the Japanese safety run-in part who received NIR178 (any dose level) in combination with PDR001 400 mg every 4 weeks

Primary: Part 1: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors

End point title	Part 1: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors[1][2]

End point description:

ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR), based on local investigator assessment per Response Evaluation Criteria for Solid Tumors (RECIST) v1.1.
For RECIST v1.1, CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.

End point type	Primary

End point timeframe:

Up to 3.9 years

Notes:

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

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the 12 selected advanced solid tumors groups defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	14
Units: percentage of participants				
number (confidence interval 90%)	27.3 (7.9 to 56.4)	25.0 (7.2 to 52.7)	0 (0.0 to 23.8)	0 (0.0 to 19.3)

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	11	27
Units: percentage of participants				
number (confidence interval 90%)	7.1 (0.4 to 29.7)	13.3 (2.4 to 36.3)	0 (0.0 to 23.8)	0 (0.0 to 10.5)

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	30	13	15
Units: percentage of participants				
number (confidence interval 90%)	3.4 (0.2 to 15.3)	10.0 (2.8 to 23.9)	0 (0.0 to 20.6)	0 (0.0 to 18.1)

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Overall Response Rate (ORR) per Cheson 2014 for DLBCL

End point title	Part 1: Overall Response Rate (ORR) per Cheson 2014 for DLBCL[3][4]

End point description:

ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR), based on local investigator assessment per Cheson 2014 criteria for diffuse large B-cell lymphoma (DLBCL).
For Cheson 2014 criteria, CR= Target nodes/nodal masses must regress to ≤1.5 cm in longest diameter (LDi), no extralymphatic sites of disease, absent non-measured lesions, organ enlargement regress to normal, no new lesions, and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative); PR= ≥50% decrease in the sum of the product of the perpendicular diameters (SPD) of up to 6 target measurable nodes, absent or regressed non-measured lesions, spleen must have regressed by >50% in length beyond normal, and no new lesions.

End point type	Primary

End point timeframe:

Up to 2.5 years

Notes:

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

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the selected lymphoma group defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: DLBCL 160 mg			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: percentage of participants				
number (confidence interval 90%)	15.4 (2.8 to 41.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Part 3: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors

End point title	Part 3: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors[5][6]

End point description:

ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR), based on local investigator assessment per RECIST v1.1.
For RECIST v1.1, CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.

End point type	Primary

End point timeframe:

Up to 0.5 years

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis were planned for this endpoint

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: percentage of participants				
number (confidence interval 90%)	16.7 (0.9 to 58.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Part 2: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors

End point title	Part 2: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors[7][8]

End point description:

ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR), based on local investigator assessment per RECIST v1.1.
For RECIST v1.1, CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.

End point type	Primary

End point timeframe:

Up to 4.7 years

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis were planned for this endpoint

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	20	20	
Units: percentage of participants				
number (confidence interval 90%)	9.1 (1.6 to 25.9)	0 (0.0 to 13.9)	10.0 (1.8 to 28.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Overall Response Rate (ORR) per iRECIST for solid tumors

End point title	Part 1: Overall Response Rate (ORR) per iRECIST for solid tumors[9]

End point description:

ORR is the percentage of patients with a best overall response of complete response (iCR) or partial response (iPR), based on local investigator assessment per immune-related RECIST (iRECIST).

End point type	Secondary

End point timeframe:

Up to 3.9 years

Notes:

[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: This endpoint only applies to the 12 selected advanced solid tumors groups defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	14
Units: percentage of participants				
number (confidence interval 90%)	36.4 (13.5 to 65.0)	25.0 (7.2 to 52.7)	0 (0.0 to 23.8)	0 (0.0 to 19.3)

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	11	27
Units: percentage of participants				
number (confidence interval 90%)	7.1 (0.4 to 29.7)	13.3 (2.4 to 36.3)	0 (0.0 to 23.8)	0 (0.0 to 10.5)

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	30	13	15
Units: percentage of participants				
number (confidence interval 90%)	3.4 (0.2 to 15.3)	10.0 (2.8 to 23.9)	0 (0.0 to 20.6)	0 (0.0 to 18.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Overall Response Rate (ORR) per iRECIST for solid tumors

End point title	Part 2: Overall Response Rate (ORR) per iRECIST for solid tumors[10]

End point description:

ORR is the percentage of patients with a best overall response of complete response (iCR) or partial response (iPR), based on local investigator assessment per immune-related RECIST (iRECIST).

End point type	Secondary

End point timeframe:

Up to 4.7 years

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	20	20	
Units: percentage of participants				
number (confidence interval 90%)	9.1 (1.6 to 25.9)	5.0 (0.3 to 21.6)	15.0 (4.2 to 34.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors

End point title	Part 1: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors[11]

End point description:

DCR is the percentage of patients with a best overall response of complete response (CR), partial response (PR), stable disease (SD) or Non-CR or Non-progressive disease (NCRNPD), based on local investigator assessment per Response Evaluation Criteria for Solid Tumors (RECIST) v1.1.

End point type	Secondary

End point timeframe:

Up to 3.9 years

Notes:

[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: This endpoint only applies to the 12 selected advanced solid tumors groups defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	14
Units: percentage of participants				
number (confidence interval 90%)	54.5 (27.1 to 80.0)	66.7 (39.1 to 87.7)	18.2 (3.3 to 47.0)	0 (0.0 to 19.3)

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	11	27
Units: percentage of participants				
number (confidence interval 90%)	28.6 (10.4 to 54.0)	40.0 (19.1 to 64.0)	63.6 (35.0 to 86.5)	25.9 (12.9 to 43.2)

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	30	13	15
Units: percentage of participants				
number (confidence interval 90%)	17.2 (7.0 to 32.9)	33.3 (19.3 to 49.9)	0 (0.0 to 20.6)	46.7 (24.4 to 70.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Overall Response Rate (ORR) per iRECIST for solid tumors

End point title	Part 3: Overall Response Rate (ORR) per iRECIST for solid tumors[12]

End point description:

ORR is the percentage of patients with a best overall response of complete response (iCR) or partial response (iPR), based on local investigator assessment per immune-related RECIST (iRECIST).

End point type	Secondary

End point timeframe:

Up to 0.5 years

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: percentage of participants				
number (confidence interval 90%)	16.7 (0.9 to 58.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Mean percentage change in PSA from baseline

End point title	Part 1: Mean percentage change in PSA from baseline[13]

End point description:

Prostate-specific antigen (PSA) levels were assessed in serum. Rising PSA is generally a manifestation of progression of prostate cancer.

End point type	Secondary

End point timeframe:

Baseline, up to 0.8 years

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the prostate cancer group defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: mCRPC 240 mg			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: percentage change in PSA from baseline				
arithmetic mean (standard deviation)	214.46 (± 329.459)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Disease Control Rate (DCR) per iRECIST for solid tumors

End point title	Part 1: Disease Control Rate (DCR) per iRECIST for solid tumors[14]

End point description:

DCR is the percentage of patients with a best overall response of complete response (iCR), partial response (iPR), stable disease (iSD) or Non-iCR or Non-unconfirmed progressive disease (NON-iCR or NON-iUPD), based on local investigator assessment per immune-related RECIST (iRECIST).

End point type	Secondary

End point timeframe:

Up to 3.9 years

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the 12 selected advanced solid tumors groups defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	14
Units: percentage of participants				
number (confidence interval 90%)	63.6 (35.0 to 86.5)	66.7 (39.1 to 87.7)	18.2 (3.3 to 47.0)	0 (0.0 to 19.3)

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	11	27
Units: percentage of participants				

number (confidence interval 90%)	35.7 (15.3 to 61.0)	40.0 (19.1 to 64.0)	54.5 (27.1 to 80.0)	25.9 (12.9 to 43.2)

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	30	13	15
Units: percentage of participants				
number (confidence interval 90%)	13.8 (4.9 to 28.8)	36.7 (22.1 to 53.3)	0 (0.0 to 20.6)	46.7 (24.4 to 70.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Disease Control Rate (DCR) per Cheson 2014 for DLBCL

End point title	Part 1: Disease Control Rate (DCR) per Cheson 2014 for

End point description:

DCR is the percentage of patients with a best overall response of complete response (CR), partial response (PR) or stable disease (SD), based on local investigator assessment per Cheson 2014 criteria for diffuse large B-cell lymphoma (DLBCL).

End point type	Secondary

End point timeframe:

Up to 2.5 years

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the selected lymphoma group defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: DLBCL 160 mg			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: percentage of participants				
number (confidence interval 90%)	23.1 (6.6 to 49.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors

End point title	Part 2: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors[16]

End point description:

DCR is the percentage of patients with a best overall response of complete response (CR), partial response (PR), stable disease (SD) or Non-CR or Non-progressive disease (NCRNPD), based on local investigator assessment per Response Evaluation Criteria for Solid Tumors (RECIST) v1.1.

End point type	Secondary

End point timeframe:

Up to 4.7 years

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	20	20	
Units: percentage of participants				
number (confidence interval 90%)	36.4 (19.6 to 56.1)	40.0 (21.7 to 60.6)	35.0 (17.7 to 55.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors

End point title	Part 3: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors[17]

End point description:

DCR is the percentage of patients with a best overall response of complete response (CR), partial response (PR), stable disease (SD) or Non-CR or Non-progressive disease (NCRNPD), based on local investigator assessment per Response Evaluation Criteria for Solid Tumors (RECIST) v1.1.

End point type	Secondary

End point timeframe:

Up to 0.5 years

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: percentage of participants				
number (confidence interval 90%)	16.7 (0.9 to 58.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Disease Control Rate (DCR) per iRECIST for solid tumors

End point title	Part 2: Disease Control Rate (DCR) per iRECIST for solid tumors[18]

End point description:

DCR is the percentage of patients with a best overall response of complete response (iCR), partial response (iPR), stable disease (iSD) or Non-iCR or Non-unconfirmed progressive disease (NON-iCR or NON-iUPD), based on local investigator assessment per immune-related RECIST (iRECIST).

End point type	Secondary

End point timeframe:

Up to 4.7 years

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	20	20	
Units: percentage of participants				
number (confidence interval 90%)	36.4 (19.6 to 56.1)	45.0 (25.9 to 65.3)	45.0 (25.9 to 65.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Duration Of Response (DOR) per RECIST v1.1 for solid tumors

End point title	Part 1: Duration Of Response (DOR) per RECIST v1.1 for solid tumors[19]

End point description:

DOR only applies to patients for whom best overall response is complete response (CR) or partial response (PR) based on local investigator assessment per RECIST v1.1. DOR is defined as the time from the date of first documented response (CR or PR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment.
DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

Up to 3.9 years

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the 12 selected advanced solid tumors groups defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	0[20]	0[21]
Units: months				
median (confidence interval 90%)	999 (999 to 999)	999 (999 to 999)	(to)	(to)

Notes:

[20] - No patients with CR or PR

[21] - No patients with CR or PR

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	0[22]	0[23]
Units: months				
median (confidence interval 90%)	999 (999 to 999)	999 (999 to 999)	(to)	(to)

Notes:

[22] - No patients with CR or PR

[23] - No patients with CR or PR

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	0[24]	0[25]
Units: months				
median (confidence interval 90%)	999 (999 to 999)	999 (999 to 999)	(to)	(to)

Notes:

[24] - No patients with CR or PR

[25] - No patients with CR or PR

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Disease Control Rate (DCR) per iRECIST for solid tumors

End point title	Part 3: Disease Control Rate (DCR) per iRECIST for solid tumors[26]

End point description:

DCR is the percentage of patients with a best overall response of complete response (iCR), partial response (iPR), stable disease (iSD) or Non-iCR or Non-unconfirmed progressive disease (NON-iCR or NON-iUPD), based on local investigator assessment per immune-related RECIST (iRECIST).

End point type	Secondary

End point timeframe:

Up to 0.5 years

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: percentage of participants				
number (confidence interval 90%)	16.7 (0.9 to 58.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Duration Of Response (DOR) per iRECIST for solid tumors

End point title	Part 1: Duration Of Response (DOR) per iRECIST for solid tumors[27]

End point description:

DOR only applies to patients for whom best overall response is complete response (iCR) or partial response (iPR) based on local investigator assessment per iRECIST. DOR is defined as the time from the date of first documented response (iCR or iPR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment.
DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

Up to 3.9 years

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the 12 selected advanced solid tumors groups defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	0[28]	0[29]
Units: months				
median (confidence interval 90%)	999 (999 to 999)	999 (999 to 999)	(to)	(to)

Notes:

[28] - No patients with CR or PR

[29] - No patients with CR or PR

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	0[30]	0[31]
Units: months				
median (confidence interval 90%)	999 (999 to 999)	999 (999 to 999)	(to)	(to)

Notes:

[30] - No patients with CR or PR

[31] - No patients with CR or PR

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	0[32]	0[33]
Units: months				
median (confidence interval 90%)	999 (999 to 999)	999 (999 to 999)	(to)	(to)

Notes:

[32] - No patients with CR or PR

[33] - No patients with CR or PR

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Duration Of Response (DOR) per iRECIST for solid tumors

End point title	Part 3: Duration Of Response (DOR) per iRECIST for solid tumors[34]

End point description:

DOR only applies to patients for whom best overall response is complete response (iCR) or partial response (iPR) based on local investigator assessment per iRECIST. DOR is defined as the time from the date of first documented response (iCR or iPR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment.
DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

Up to 0.5 years

Notes:

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: months				
median (confidence interval 90%)	999 (999 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Duration Of Response (DOR) per RECIST v1.1 for solid tumors

End point title	Part 3: Duration Of Response (DOR) per RECIST v1.1 for solid tumors[35]

End point description:

DOR only applies to patients for whom best overall response is complete response (CR) or partial response (PR) based on local investigator assessment per RECIST v1.1. DOR is defined as the time from the date of first documented response (CR or PR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment.
DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

Up to 0.5 years

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: months				
median (confidence interval 90%)	999 (999 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Duration Of Response (DOR) per iRECIST for solid tumors

End point title	Part 2: Duration Of Response (DOR) per iRECIST for solid tumors[36]

End point description:

DOR only applies to patients for whom best overall response is complete response (iCR) or partial response (iPR) based on local investigator assessment per iRECIST. DOR is defined as the time from the date of first documented response (iCR or iPR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment.
DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

Up to 4.7 years

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	1	3	
Units: months				
median (confidence interval 90%)	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Duration Of Response (DOR) per RECIST v1.1 for solid tumors

End point title	Part 2: Duration Of Response (DOR) per RECIST v1.1 for solid tumors[37]

End point description:

DOR only applies to patients for whom best overall response is complete response (CR) or partial response (PR) based on local investigator assessment per RECIST v1.1. DOR is defined as the time from the date of first documented response (CR or PR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment.
DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

Up to 4.7 years

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	0[38]	2	
Units: months				
median (confidence interval 90%)	999 (999 to 999)	(to)	999 (999 to 999)	

Notes:

[38] - No patients with CR or PR

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Duration Of Response (DOR) per Cheson 2014 for DLBCL

End point title	Part 1: Duration Of Response (DOR) per Cheson 2014 for DLBCL[39]

End point description:

DOR only applies to patients for whom best overall response is complete response (CR) or partial response (PR) based on local investigator assessment per Cheson 2014 criteria for DLBCL. DOR is defined as the time from the date of first documented response (CR or PR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment. DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

Up to 2.5 years

Notes:

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the selected lymphoma group defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: DLBCL 160 mg			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: months				
median (confidence interval 90%)	999 (999 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors

End point title	Part 1: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors[40]

End point description:

PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause, whichever happened first. If a patient did not have an event, PFS was censored at the date of the last adequate tumor assessment. Tumor response was based on local investigator assessment per RECIST v1.1.
PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.

End point type	Secondary

End point timeframe:

Up to 3.9 years

Notes:

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the 12 selected advanced solid tumors groups defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	14
Units: months				
median (confidence interval 90%)	3.5 (1.9 to 15.4)	7.2 (1.8 to 8.6)	1.9 (1.7 to 2.0)	1.7 (1.6 to 1.7)

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	11	27
Units: months				
median (confidence interval 90%)	1.9 (1.7 to 3.5)	2.0 (1.6 to 3.7)	3.5 (1.7 to 3.7)	1.7 (1.6 to 1.9)

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	30	13	15
Units: months				
median (confidence interval 90%)	1.9 (1.7 to 2.0)	1.7 (1.6 to 1.9)	1.8 (1.6 to 1.9)	3.7 (1.7 to 5.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Progression-Free Survival (PFS) per iRECIST for solid tumors

End point title	Part 1: Progression-Free Survival (PFS) per iRECIST for solid tumors[41]

End point description:

PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause, whichever happened first. If a patient did not have an event, PFS was censored at the date of the last adequate tumor assessment. Tumor response was based on local investigator assessment per iRECIST.
PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

Up to 3.9 years

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the 12 selected advanced solid tumors groups defined in the

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	14
Units: months				
median (confidence interval 90%)	8.7 (2.1 to 999)	7.2 (1.8 to 999)	1.9 (1.7 to 2.0)	1.7 (1.1 to 1.7)

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	11	27
Units: months				
median (confidence interval 90%)	2.1 (1.7 to 3.5)	2.0 (1.6 to 3.7)	3.5 (1.7 to 3.7)	1.8 (1.6 to 2.0)

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	30	13	15
Units: months				
median (confidence interval 90%)	1.9 (1.7 to 2.0)	1.8 (1.6 to 3.5)	1.8 (1.6 to 1.9)	3.7 (1.7 to 5.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Progression-Free Survival (PFS) per iRECIST for solid tumors

End point title	Part 3: Progression-Free Survival (PFS) per iRECIST for solid tumors[42]

End point description:

PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause, whichever happened first. If a patient did not have an event, PFS was censored at the date of the last adequate tumor assessment. Tumor response was based on local investigator assessment per iRECIST.
PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.

End point type	Secondary

End point timeframe:

Up to 0.5 years

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: months				
median (confidence interval 90%)	1.6 (0.9 to 1.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors

End point title	Part 3: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors[43]

End point description:

PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause, whichever happened first. If a patient did not have an event, PFS was censored at the date of the last adequate tumor assessment. Tumor response was based on local investigator assessment per RECIST v1.1.
PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.

End point type	Secondary

End point timeframe:

Up to 0.5 years

Notes:

[43] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: months				
median (confidence interval 90%)	1.6 (0.9 to 1.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors

End point title	Part 2: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors[44]

End point description:

PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause, whichever happened first. If a patient did not have an event, PFS was censored at the date of the last adequate tumor assessment. Tumor response was based on local investigator assessment per RECIST v1.1.
PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.

End point type	Secondary

End point timeframe:

Up to 4.7 years

Notes:

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	20	20	
Units: months				
median (confidence interval 90%)	2.0 (1.8 to 3.8)	2.1 (1.7 to 3.7)	1.9 (1.7 to 3.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Progression-Free Survival (PFS) per Cheson 2014 for DLBCL

End point title	Part 1: Progression-Free Survival (PFS) per Cheson 2014 for DLBCL[45]

End point description:

PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause, whichever happened first. If a patient did not have an event, PFS was censored at the date of the last adequate tumor assessment. Tumor response was based on local investigator assessment per Cheson 2014 for DLBCL.
PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.

End point type	Secondary

End point timeframe:

Up to 2.5 years

Notes:

[45] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the selected lymphoma group defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: DLBCL 160 mg			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: months				
median (confidence interval 90%)	1.7 (1.4 to 2.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Progression-Free Survival (PFS) per iRECIST for solid tumors

End point title	Part 2: Progression-Free Survival (PFS) per iRECIST for solid tumors[46]

End point description:

PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause, whichever happened first. If a patient did not have an event, PFS was censored at the date of the last adequate tumor assessment. Tumor response was based on local investigator assessment per iRECIST.
PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.

End point type	Secondary

End point timeframe:

Up to 4.7 years

Notes:

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	20	20	
Units: months				
median (confidence interval 90%)	2.1 (1.8 to 3.8)	2.2 (1.8 to 3.7)	2.8 (1.7 to 9.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: 2-year Overall Survival (OS)

End point title	Part 1: 2-year Overall Survival (OS)[47]

End point description:

OS represents the percentage of participants who are alive after the start of study treatment. OS at 2 years was estimated using the Kaplan-Meier method as defined in the statistical analysis plan (SAP). Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

2 years

Notes:

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

Justification: This endpoint only applies to the 13 selected cancer groups (advanced solid tumors and lymphoma) defined in the study protocol for efficacy assessment in Part 1

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	14
Units: percentage of participants				
number (confidence interval 90%)	63.6 (35.5 to 82.1)	42.1 (14.6 to 67.8)	27.3 (8.9 to 49.8)	999 (999 to 999)

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	11	27
Units: percentage of participants				
number (confidence interval 90%)	36.1 (15.0 to 57.9)	33.3 (15.0 to 52.9)	15.3 (1.9 to 41.2)	22.1 (9.4 to 38.2)

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: DLBCL 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	30	13	13
Units: percentage of participants				
number (confidence interval 90%)	14.3 (4.3 to 29.9)	30.8 (16.0 to 46.9)	999 (999 to 999)	23.1 (7.5 to 43.6)

End point values	Part 1: mCRPC 240 mg			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: percentage of participants				
number (confidence interval 90%)	31.4 (10.8 to 54.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change from baseline in CD8 percent marker area in tumor tissue

End point title	Part 1: Change from baseline in CD8 percent marker area in tumor tissue[48]

End point description:

The tumor expression of CD8 was measured by immunohistochemical (IHC) methods. Newly obtained pre- and on-treatment paired tumor samples were required and collected at screening and after approximately two cycles of therapy.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary

End point timeframe:

Screening and on-treatment (Cycle 2 Day 1 or Day 15). The duration of one cycle was 28 days.

Notes:

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 1. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status

End point values	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	5	3	2
Units: CD8 percent marker area				
arithmetic mean (standard deviation)	10.93 (± 14.227)	10.53 (± 12.456)	0.70 (± 2.645)	-0.81 (± 0.537)

End point values	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	4	7
Units: CD8 percent marker area				
arithmetic mean (standard deviation)	0.96 (± 1.345)	1.63 (± 2.372)	-0.42 (± 1.477)	0.70 (± 1.141)

End point values	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: DLBCL 160 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	10	4	1
Units: CD8 percent marker area				
arithmetic mean (standard deviation)	-0.01 (± 1.164)	4.86 (± 3.751)	0.16 (± 0.540)	7.84 (± 999)

End point values	Part 1: mCRPC 240 mg			

Subject group type	Reporting group			
Number of subjects analysed	4			
Units: CD8 percent marker area				
arithmetic mean (standard deviation)	2.67 (± 4.156)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: 2-year Overall Survival (OS)

End point title	Part 3: 2-year Overall Survival (OS)[49]

End point description:

OS represents the percentage of participants who are alive after the start of study treatment. OS at 2 years was estimated using the Kaplan-Meier method as defined in the statistical analysis plan.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not available'). Therefore, not available values because of insufficient number of participants with events are indicated as '999'.

End point type	Secondary

End point timeframe:

2 years

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: percentage of participants				
number (confidence interval 90%)	999 (999 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: 2-year Overall Survival (OS)

End point title	Part 2: 2-year Overall Survival (OS)[50]

End point description:

OS represents the percentage of participants who are alive after the start of study treatment. OS at 2 years was estimated using the Kaplan-Meier method as defined in the statistical analysis plan.

End point type	Secondary

End point timeframe:

2 years

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	20	20	
Units: percentage of participants				
number (confidence interval 90%)	33.6 (15.5 to 52.9)	22.7 (7.5 to 42.7)	39.7 (20.3 to 58.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change from baseline in CD8 percent marker area in tumor tissue

End point title	Part 2: Change from baseline in CD8 percent marker area in tumor tissue[51]

End point description:

The tumor expression of CD8 was measured by immunohistochemical (IHC) methods. Newly obtained pre- and on-treatment paired tumor samples were required and collected at screening and after approximately two cycles of therapy.

End point type	Secondary

End point timeframe:

Screening and on-treatment (Cycle 2 Day 1 or Day 15). The duration of one cycle was 28 days.

Notes:

[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	4	4	
Units: CD8 percent marker area				
arithmetic mean (standard deviation)	3.81 (± 4.551)	-2.35 (± 5.586)	1.23 (± 2.955)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: Change from baseline in CD8 percent marker area in tumor tissue

End point title	Part 3: Change from baseline in CD8 percent marker area in tumor tissue[52]

End point description:

The tumor expression of CD8 was measured by immunohistochemical (IHC) methods. Newly obtained pre- and on-treatment paired tumor samples were required and collected at screening and after approximately two cycles of therapy.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary

End point timeframe:

Screening and on-treatment (Cycle 2 Day 1 or Day 15). The duration of one cycle was 28 days.

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 3

End point values	Part 3: TNBC 160 mg cont			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: CD8 percent marker area				
arithmetic mean (standard deviation)	0.26 (± 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1, 2 and 3: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

End point title	Part 1, 2 and 3: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period[53]

End point description:

Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs.
The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.

End point type	Secondary

End point timeframe:

Up to 4 years (Part 1), 4.8 years (Part 2) and 0.6 years (Part 3)

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 1, 2 and 3. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status

End point values	Part 1: RCC naïve 160 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N pre 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	14	12
Units: participants				
AEs	10	14	14	12

Treatment-related AEs	7	9	9	9
SAEs	3	9	7	5
Treatment-related SAEs	0	2	1	2
Fatal SAEs	1	1	0	1
Treatment-related fatal SAEs	0	0	0	0

End point values	Part 1: TNBC 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	13	6	15
Units: participants				
AEs	29	13	5	14
Treatment-related AEs	23	11	2	12
SAEs	11	6	0	4
Treatment-related SAEs	2	2	0	2
Fatal SAEs	1	1	0	0
Treatment-related fatal SAEs	0	0	0	0

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	20	20	6
Units: participants				
AEs	22	18	18	6
Treatment-related AEs	15	14	9	4
SAEs	11	7	7	3
Treatment-related SAEs	6	3	0	0
Fatal SAEs	1	2	0	0
Treatment-related fatal SAEs	0	0	0	0

End point values	Part 1: RCC naïve + pre 240 mg	Part 1: H-N naïve + pre 160 mg	Part 1: MSS CRC 160 mg	Part 1: Melanoma naïve + pre 160 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	23	26	58	16
Units: participants				
AEs	22	26	57	15
Treatment-related AEs	16	16	34	6
SAEs	7	15	28	3
Treatment-related SAEs	2	3	7	0
Fatal SAEs	0	2	3	0
Treatment-related fatal SAEs	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1, 2 and 3: Number of participants with dose reductions and dose interruptions of NIR178

End point title	Part 1, 2 and 3: Number of participants with dose reductions and dose interruptions of NIR178[54]

End point description:

Number of participants with at least one dose reduction of NIR178 and number of participants with at least one dose interruption of NIR178. Dose or schedule adjustments were permitted for patients who did not tolerate the protocol-specified dosing schedule.

End point type	Secondary

End point timeframe:

Up to 3.9 years (Part 1), 4.7 years (Part 2) and 0.5 years (Part 3)

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 1, 2 and 3. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status

End point values	Part 1: RCC naïve 160 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N pre 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	14	12
Units: participants				
At least one dose reduction	2	0	2	1
At least one dose interruption	6	2	8	3

End point values	Part 1: TNBC 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	13	6	15
Units: participants				
At least one dose reduction	3	1	0	2
At least one dose interruption	9	3	1	5

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	20	20	6
Units: participants				
At least one dose reduction	2	1	1	0
At least one dose interruption	8	5	4	0

End point values	Part 1: RCC naïve + pre 240 mg	Part 1: H-N naïve + pre 160 mg	Part 1: MSS CRC 160 mg	Part 1: Melanoma naïve + pre 160 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	23	26	58	16
Units: participants				
At least one dose reduction	1	8	7	1
At least one dose interruption	9	12	20	3

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1, 2 and 3: Number of participants with dose reductions and dose interruptions of PDR001

End point title	Part 1, 2 and 3: Number of participants with dose reductions and dose interruptions of PDR001[55]

End point description:

Number of participants with at least one dose reduction of PDR001 and number of participants with at least one dose interruption of PDR001. Dose or schedule adjustments were permitted for patients who did not tolerate the protocol-specified dosing schedule. Dose reductions were not permitted for PDR001.

End point type	Secondary

End point timeframe:

Up to 3.9 years (Part 1), 4.7 years (Part 2) and 0.5 years (Part 3)

Notes:

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 1, 2 and 3. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status

End point values	Part 1: RCC naïve 160 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N pre 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	14	12
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	6	1	6	1

End point values	Part 1: TNBC 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	13	6	15
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	8	0	0	2

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	20	20	6
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	6	4	2	0

End point values	Part 1: RCC naïve + pre 240 mg	Part 1: H-N naïve + pre 160 mg	Part 1: MSS CRC 160 mg	Part 1: Melanoma naïve + pre 160 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	23	26	58	16
Units: participants				
At least one dose reduction	0	0	0	0
At least one dose interruption	7	9	13	2

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1, 2 and 3: Dose intensity of NIR178

End point title	Part 1, 2 and 3: Dose intensity of NIR178[56]

End point description:

Dose intensity of NIR178 was calculated as cumulative actual dose in milligrams divided by duration of exposure in days.

End point type	Secondary

End point timeframe:

Up to 3.9 years (Part 1), 4.7 years (Part 2) and 0.5 years (Part 3)

Notes:

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

Justification: This endpoint only applies to Part 1, 2 and 3. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status

End point values	Part 1: RCC naïve 160 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N pre 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	14	12
Units: mg/day				
median (full range (min-max))	316.7 (187 to 320)	320.0 (241 to 320)	295.7 (140 to 320)	480.0 (272 to 480)

End point values	Part 1: TNBC 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	13	6	15
Units: mg/day				
median (full range (min-max))	320.0 (179 to 320)	320.0 (233 to 320)	480.0 (363 to 480)	480.0 (382 to 496)

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	20	20	6
Units: mg/day				
median (full range (min-max))	320.0 (137 to 320)	160.0 (96 to 173)	160.0 (71 to 189)	320.0 (319 to 320)

End point values	Part 1: RCC naïve + pre 240 mg	Part 1: H-N naïve + pre 160 mg	Part 1: MSS CRC 160 mg	Part 1: Melanoma naïve + pre 160 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	23	26	58	16
Units: mg/day				
median (full range (min-max))	477.3 (321 to 480)	309.8 (141 to 320)	320.0 (134 to 320)	320.0 (208 to 320)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1, 2 and 3: Dose intensity of PDR001

End point title	Part 1, 2 and 3: Dose intensity of PDR001[57]

End point description:

Dose intensity of PDR001 was calculated as cumulative actual dose in milligrams divided by duration of exposure in days and then multiplied by 28 days.

End point type	Secondary

End point timeframe:

Up to 3.9 years (Part 1), 4.7 years (Part 2) and 0.5 years (Part 3)

Notes:

[57] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 1, 2 and 3. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status

End point values	Part 1: RCC naïve 160 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N pre 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	14	12
Units: mg/28 days				
median (full range (min-max))	394.2 (300 to 400)	400.0 (395 to 400)	393.1 (350 to 400)	400.0 (365 to 407)

End point values	Part 1: TNBC 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	13	6	15
Units: mg/28 days				
median (full range (min-max))	400.0 (305 to 404)	400.0 (386 to 400)	400.0 (400 to 400)	400.0 (378 to 404)

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	20	20	6
Units: mg/28 days				
median (full range (min-max))	400.0 (224 to 406)	400.0 (300 to 401)	400.0 (387 to 410)	400.0 (400 to 400)

End point values	Part 1: RCC naïve + pre 240 mg	Part 1: H-N naïve + pre 160 mg	Part 1: MSS CRC 160 mg	Part 1: Melanoma naïve + pre 160 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	23	26	58	16
Units: mg/28 days				

median (full range (min-max))	396.2 (267 to 431)	398.2 (319 to 402)	400.0 (236 to 405)	400.0 (389 to 406)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1, 2 and 3: Number of participants with anti-PDR001 antibodies

End point title	Part 1, 2 and 3: Number of participants with anti-PDR001 antibodies[58]

End point description:

PDR001 immunogenicity was evaluated in serum samples. Patient anti-drug antibodies (ADA) status was defined as follows:
• ADA-negative at baseline: ADA-negative sample at baseline
• ADA-positive at baseline: ADA-positive sample at baseline
• ADA-negative post-baseline: ADA-negative sample at baseline and at least 1 post-baseline sample, all of which are ADA-negative samples
• Treatment-reduced ADA-positive: ADA-positive sample at baseline and at least 1 post-baseline sample, all of which are ADA-negative samples
• Treatment-induced ADA-positive: ADA-negative sample at baseline and at least 1 treatment-induced ADA-positive sample
• Treatment-boosted ADA-positive: ADA-positive sample at baseline and at least 1 treatment-boosted ADA-positive sample
• ADA-inconclusive: patient who does not qualify for any of the above definitions or a patient for which the baseline sample is missing

End point type	Secondary

End point timeframe:

Up to approximately 5 years

Notes:

[58] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to Part 1, 2 and 3. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status

End point values	Part 1: RCC naïve 160 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N pre 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	13	11
Units: participants				
ADA-negative at baseline	11	12	13	11
ADA-positive at baseline	0	0	0	0
ADA-negative post-baseline	10	11	12	11
Treatment-reduced ADA-positive	0	0	0	0
Treatment-induced ADA-positive	1	1	1	0
Treatment-boosted ADA-positive	0	0	0	0
ADA-inconclusive	0	0	0	0

End point values	Part 1: TNBC 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	10	6	13
Units: participants				
ADA-negative at baseline	27	10	6	13
ADA-positive at baseline	0	0	0	0
ADA-negative post-baseline	25	10	6	11
Treatment-reduced ADA-positive	0	0	0	0
Treatment-induced ADA-positive	2	0	0	2
Treatment-boosted ADA-positive	0	0	0	0
ADA-inconclusive	0	0	0	0

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	19	17	6
Units: participants				
ADA-negative at baseline	21	19	17	6
ADA-positive at baseline	0	0	0	0
ADA-negative post-baseline	21	14	14	5
Treatment-reduced ADA-positive	0	0	0	0
Treatment-induced ADA-positive	0	5	3	1
Treatment-boosted ADA-positive	0	0	0	0
ADA-inconclusive	0	0	0	0

End point values	Part 1: RCC naïve + pre 240 mg	Part 1: H-N naïve + pre 160 mg	Part 1: MSS CRC 160 mg	Part 1: Melanoma naïve + pre 160 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	23	24	52	13
Units: participants				
ADA-negative at baseline	23	24	49	13
ADA-positive at baseline	0	0	3	0
ADA-negative post-baseline	23	22	48	13
Treatment-reduced ADA-positive	0	0	1	0
Treatment-induced ADA-positive	0	2	1	0
Treatment-boosted ADA-positive	0	0	0	0
ADA-inconclusive	0	0	2	0

Statistical analyses

No statistical analyses for this end point

Secondary: Japan Safety Run-in: Number of participants with Dose-Limiting Toxicities (DLTs)

End point title	Japan Safety Run-in: Number of participants with Dose-Limiting Toxicities (DLTs)[59]

End point description:

A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as unrelated to disease, disease progression, inter-current illness or concomitant medications, which occurs within the first 28 days of treatment with NIR178 as single agent or in combination with PDR001 during the Japan safety run-in part of the study. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher.

End point type	Secondary

End point timeframe:

28 days

Notes:

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the Japan Safety Run-in

End point values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	3	3	
Units: participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: All study parts: Maximum observed plasma concentration (Cmax) of NIR178

End point title	All study parts: Maximum observed plasma concentration (Cmax) of NIR178[60]

End point description:

Pharmacokinetic (PK) parameters were calculated based on NIR178 plasma concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed plasma concentration following a dose.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days

Notes:

[60] - 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: Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

End point values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3[61]	3[62]	3[63]	206[64]
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (all regimens)	81.8 (± 99.9)	30.1 (± 32.9)	234 (± 70.9)	129 (± 335.0)
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (± 999)	999 (± 999)	999 (± 999)	576 (± 83.1)
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (± 999)	999 (± 999)	999 (± 999)	392 (± 212.7)
Cycle 1 Day 28 (continuous)	311 (± 91.5)	167 (± 40.9)	3760 (± 39.6)	297 (± 291.4)

Notes:

[61] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[62] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[63] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[64] - n=206 (C1D1), 17 (C1D7), 11 (C1D14), 100 (C1D28)

End point values	NIR178 240 mg capsule in Non-Japanese (Part 1)	NIR178 160 mg tablet in Non-Japanese (Part 3)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54[65]	6[66]		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (all regimens)	160 (± 247.8)	75.1 (± 382.3)		
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (± 999)	999 (± 999)		
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (± 999)	999 (± 999)		
Cycle 1 Day 28 (continuous)	622 (± 154.3)	723 (± 295.5)		

Notes:

[65] - n=54 (C1D1), 0 (C1D7), 0 (C1D14), 41 (C1D28)

[66] - n=6 (C1D1), 0 (C1D7), 0 (C1D14), 4 (C1D28)

Statistical analyses

No statistical analyses for this end point

Secondary: Japan Safety Run-in: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

End point title	Japan Safety Run-in: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period[67]

End point description:

Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs.
The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.

End point type	Secondary

End point timeframe:

Up to 0.7 years

Notes:

[67] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only applies to the Japan Safety Run-in

End point values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	3	3	
Units: participants				
AEs	3	3	3	
Treatment-related AEs	0	2	1	
SAEs	2	1	1	
Treatment-related SAEs	0	1	0	
Fatal SAEs	0	0	0	
Treatment-related fatal SAEs	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: All study parts: Time to reach maximum plasma concentration (Tmax) of NIR178

End point title	All study parts: Time to reach maximum plasma concentration (Tmax) of NIR178[68]

End point description:

Pharmacokinetic (PK) parameters were calculated based on NIR178 plasma concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) plasma concentration following a dose. Actual recorded sampling times were considered for the calculations.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days

Notes:

[68] - 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: Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

End point values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3[69]	3[70]	3[71]	206[72]
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (all regimens)	1.50 (1.47 to 1.50)	1.50 (0.583 to 3.95)	3.00 (2.03 to 3.03)	2.00 (0.250 to 8.00)

Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)	1.45 (0.50 to 4.00)
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)	1.97 (0.550 to 7.67)
Cycle 1 Day 28 (continuous)	1.43 (0.50 to 1.48)	1.45 (0.50 to 1.50)	2.87 (1.92 to 4.00)	2.00 (0.267 to 8.00)

Notes:

[69] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[70] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[71] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[72] - n=206 (C1D1), 17 (C1D7), 11 (C1D14), 100 (C1D28)

End point values	NIR178 240 mg capsule in Non-Japanese (Part 1)	NIR178 160 mg tablet in Non-Japanese (Part 3)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54[73]	6[74]		
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (all regimens)	2.13 (0.50 to 8.00)	1.50 (0.450 to 4.05)		
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (999 to 999)	999 (999 to 999)		
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (999 to 999)	999 (999 to 999)		
Cycle 1 Day 28 (continuous)	2.02 (0.250 to 7.60)	1.52 (0.50 to 3.00)		

Notes:

[73] - n=54 (C1D1), 0 (C1D7), 0 (C1D14), 41 (C1D28)

[74] - n=6 (C1D1), 0 (C1D7), 0 (C1D14), 4 (C1D28)

Statistical analyses

No statistical analyses for this end point

Secondary: All study parts: Area under the plasma concentration-time curve from time zero to 12 hours post dose (AUC0-12hr) of NIR178

End point title	All study parts: Area under the plasma concentration-time curve from time zero to 12 hours post dose (AUC0-12hr) of NIR178[75]

End point description:

PK parameters were calculated based on NIR178 plasma concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUC0-12hr calculation.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days

Notes:

[75] - 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: Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

End point values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3[76]	2[77]	1[78]	95[79]
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (all regimens)	170 (± 124.9)	63.3 (± 88.0)	550 (± 999)	295 (± 198.3)
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (± 999)	999 (± 999)	999 (± 999)	1260 (± 63.2)
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (± 999)	999 (± 999)	999 (± 999)	1680 (± 94.4)
Cycle 1 Day 28 (continuous)	697 (± 131.8)	242 (± 13.5)	12800 (± 999)	918 (± 187.5)

Notes:

[76] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[77] - n=2 (C1D1), 0 (C1D7), 0 (C1D14), 2 (C1D28)

[78] - n=1 (C1D1), 0 (C1D7), 0 (C1D14), 1 (C1D28)

[79] - n=95 (C1D1), 12 (C1D7), 7 (C1D14), 63 (C1D28)

End point values	NIR178 240 mg capsule in Non-Japanese (Part 1)	NIR178 160 mg tablet in Non-Japanese (Part 3)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	24[80]	4[81]		
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (all regimens)	487 (± 126.3)	232 (± 437.4)		
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (± 999)	999 (± 999)		
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (± 999)	999 (± 999)		
Cycle 1 Day 28 (continuous)	1620 (± 147.9)	938 (± 414.2)		

Notes:

[80] - n=24 (C1D1), 0 (C1D7), 0 (C1D14), 24 (C1D28)

[81] - n=4 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

Statistical analyses

No statistical analyses for this end point

Secondary: All study parts: Maximum observed plasma concentration (Cmax) of NJI765 (NIR178 metabolite)

End point title	All study parts: Maximum observed plasma concentration (Cmax) of NJI765 (NIR178 metabolite)[82]

End point description:

NJI765 is a NIR178 metabolite. PK parameters were calculated based on NJI765 plasma concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed plasma concentration following a dose.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days

Notes:

[82] - 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: Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

End point values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2[83]	3[84]	3[85]	201[86]
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (all regimens)	999 (± 999)	25.9 (± 77.0)	28.5 (± 99.9)	25.5 (± 85.2)
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (± 999)	999 (± 999)	999 (± 999)	62.9 (± 39.4)
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (± 999)	999 (± 999)	999 (± 999)	71.3 (± 43.3)
Cycle 1 Day 28 (continuous)	45.6 (± 74.0)	53.9 (± 64.2)	111 (± 36.6)	42.6 (± 77.3)

Notes:

[83] - n=0 (C1D1), 0 (C1D7), 0 (C1D14), 2 (C1D28)

[84] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[85] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[86] - n=201 (C1D1), 17 (C1D7), 8 (C1D14), 96 (C1D28)

End point values	NIR178 240 mg capsule in Non-Japanese (Part 1)	NIR178 160 mg tablet in Non-Japanese (Part 3)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54[87]	6[88]		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (all regimens)	33.7 (± 64.2)	20.1 (± 99.2)		
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (± 999)	999 (± 999)		
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (± 999)	999 (± 999)		
Cycle 1 Day 28 (continuous)	77.3 (± 49.9)	54.1 (± 102.4)		

Notes:

[87] - n=54 (C1D1), 0 (C1D7), 0 (C1D14), 40 (C1D28)

[88] - n=6 (C1D1), 0 (C1D7), 0 (C1D14), 4 (C1D28)

Statistical analyses

No statistical analyses for this end point

Secondary: All study parts: Time to reach maximum plasma concentration (Tmax) of NJI765 (NIR178 metabolite)

End point title	All study parts: Time to reach maximum plasma concentration (Tmax) of NJI765 (NIR178 metabolite)[89]

End point description:

NJI765 is a NIR178 metabolite. Pharmacokinetic (PK) parameters were calculated based on NJI765 plasma concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) plasma concentration following a dose. Actual recorded sampling times were considered for the calculations.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating ‘not

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

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days

Notes:

[89] - 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: Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

End point values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2[90]	3[91]	3[92]	201[93]
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (all regimens)	999 (999 to 999)	1.95 (0.583 to 2.00)	3.00 (2.03 to 3.03)	2.00 (0.250 to 8.05)
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)	1.50 (0.50 to 4.00)
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)	1.98 (0.550 to 3.00)
Cycle 1 Day 28 (continuous)	2.23 (1.43 to 3.02)	1.45 (0.50 to 1.50)	2.87 (1.92 to 4.00)	2.00 (0.483 to 8.03)

Notes:

[90] - n=0 (C1D1), 0 (C1D7), 0 (C1D14), 2 (C1D28)

[91] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[92] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 3 (C1D28)

[93] - n=201 (C1D1), 17 (C1D7), 8 (C1D14), 96 (C1D28)

End point values	NIR178 240 mg capsule in Non-Japanese (Part 1)	NIR178 160 mg tablet in Non-Japanese (Part 3)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54[94]	6[95]		
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1 (all regimens)	2.08 (0.50 to 8.00)	2.10 (0.450 to 4.05)		
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (999 to 999)	999 (999 to 999)		
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (999 to 999)	999 (999 to 999)		
Cycle 1 Day 28 (continuous)	2.10 (0.250 to 7.88)	0.750 (0.50 to 2.03)		

Notes:

[94] - n=54 (C1D1), 0 (C1D7), 0 (C1D14), 40 (C1D28)

[95] - n=6 (C1D1), 0 (C1D7), 0 (C1D14), 4 (C1D28)

Statistical analyses

No statistical analyses for this end point

Secondary: All study parts: Area under the plasma concentration-time curve from time zero to 12 hours post dose (AUC0-12hr) of NJI765 (NIR178 metabolite)

End point title	All study parts: Area under the plasma concentration-time curve from time zero to 12 hours post dose (AUC0-12hr) of NJI765 (NIR178 metabolite)[96]

End point description:

NJI765 is a NIR178 metabolite. PK parameters were calculated based on NJI765 plasma concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUC0-12hr calculation.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days

Notes:

[96] - 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: Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

End point values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[97]	3[98]	1[99]	62[100]
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (all regimens)	()	117 (± 68.2)	119 (± 999)	98.2 (± 87.1)
Cycle 1 Day 7 (1 wk-on/1 wk-off)	()	999 (± 999)	999 (± 999)	243 (± 57.5)
Cycle 1 Day 14 (2 wk-on/2 wk-off)	()	999 (± 999)	999 (± 999)	288 (± 23.7)
Cycle 1 Day 28 (continuous)	()	277 (± 69.0)	362 (± 999)	214 (± 76.6)

Notes:

[97] - No data available

[98] - n=3 (C1D1), 0 (C1D7), 0 (C1D14), 2 (C1D28)

[99] - n=1 (C1D1), 0 (C1D7), 0 (C1D14), 1 (C1D28)

[100] - n=62 (C1D1), 8 (C1D7), 5 (C1D14), 41 (C1D28)

End point values	NIR178 240 mg capsule in Non-Japanese (Part 1)	NIR178 160 mg tablet in Non-Japanese (Part 3)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20[101]	2[102]		
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (all regimens)	122 (± 75.6)	77.1 (± 35.9)		
Cycle 1 Day 7 (1 wk-on/1 wk-off)	999 (± 999)	999 (± 999)		
Cycle 1 Day 14 (2 wk-on/2 wk-off)	999 (± 999)	999 (± 999)		
Cycle 1 Day 28 (continuous)	382 (± 43.7)	226 (± 147.0)		

Notes:

[101] - n=20 (C1D1), 0 (C1D7), 0 (C1D14), 16 (C1D28)

[102] - n=2 (C1D1), 0 (C1D7), 0 (C1D14), 2 (C1D28)

Statistical analyses

No statistical analyses for this end point

Secondary: All study parts: Time to reach maximum serum concentration (Tmax) of PDR001

End point title	All study parts: Time to reach maximum serum concentration (Tmax) of PDR001

End point description:

PK parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) serum concentration following a dose. Actual recorded sampling times were considered for the calculations.

End point type	Secondary

End point timeframe:

First dose (Cycle 1 Day 1 or Cycle 2 Day 1 for Japanese patients treated with NIR178 80 or 160 mg) and Cycle 3 Day 1: pre-infusion, 1, 168, 336, 504 and 672 hours after end of infusion. Average duration of infusion=30 minutes. 1 cycle=28 days

End point values	Non-Japanese patients	Japanese patients		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	257[103]	3[104]		
Units: hours				
median (full range (min-max))				
First dose (Cycle 1 Day 1 or Cycle 2 Day 1)	1.50 (0.333 to 718)	1.50 (1.48 to 1.52)		
Cycle 3 Day 1	1.50 (0.550 to 358)	1.65 (1.65 to 1.65)		

Notes:

[103] - n=257 (first dose), 132 (C3D1)

[104] - n=3 (first dose), 1 (C3D1)

Statistical analyses

No statistical analyses for this end point

Secondary: All study parts: Maximum observed serum concentration (Cmax) of PDR001

End point title	All study parts: Maximum observed serum concentration (Cmax) of PDR001

End point description:

PK parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed serum concentration following a dose. Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating ‘not applicable’). Therefore, not applicable values are indicated as ‘999’.

End point type	Secondary

End point timeframe:

First dose (Cycle 1 Day 1 or Cycle 2 Day 1 for Japanese patients treated with NIR178 80 or 160 mg) and Cycle 3 Day 1: pre-infusion, 1, 168, 336, 504 and 672 hours after end of infusion. Average duration of infusion=30 minutes. 1 cycle=28 days

End point values	Non-Japanese patients	Japanese patients		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	257[105]	3[106]		
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
First dose (Cycle 1 Day 1 or Cycle 2 Day 1)	93.2 (± 30.8)	85.0 (± 12.8)		
Cycle 3 Day 1	126 (± 37.4)	119 (± 999)		

Notes:

[105] - n=257 (first dose), 132 (C3D1)

[106] - n=3 (first dose), 1 (C3D1)

Statistical analyses

No statistical analyses for this end point

Secondary: All study parts: Area under the serum concentration-time curve from time zero to 28 days post dose (AUC0-28day) of PDR001

End point title	All study parts: Area under the serum concentration-time curve from time zero to 28 days post dose (AUC0-28day) of PDR001

End point description:

PK parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUC0-28day calculation.
Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

End point type	Secondary

End point timeframe:

First dose (Cycle 1 Day 1 or Cycle 2 Day 1 for Japanese patients treated with NIR178 80 or 160 mg) and Cycle 3 Day 1: pre-infusion, 1, 168, 336, 504 and 672 hours after end of infusion. Average duration of infusion=30 minutes. 1 cycle=28 days

End point values	Non-Japanese patients	Japanese patients		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	236[107]	3[108]		
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)				
First dose (Cycle 1 Day 1 or Cycle 2 Day 1)	1140 (± 31.2)	1110 (± 13.9)		
Cycle 3 Day 1	2030 (± 41.3)	999 (± 999)		

Notes:

[107] - n=236 (first dose), 36 (C3D1)

[108] - n=3 (first dose), 0 (C3D1)

Statistical analyses

No statistical analyses for this end point

Post-hoc: All-Collected Deaths

End point title	All-Collected Deaths[109]

End point description:

On-treatment and post-treatment safety follow-up deaths were collected from first dose of study medication to 150 days after last dose of NIR178+PDR001. Survival follow-up deaths were collected from 151 days after last dose of NIR178+PDR001 until end of study. All deaths refer to the sum of on-treatment and post-treatment safety follow-up deaths plus survival follow-up deaths.

End point type	Post-hoc

End point timeframe:

On-treatment and safety follow-up (FU) deaths: up to 4.3 years (Part 1), 5.1 years (Part 2), 0.9 years (Part 3) and 0.9 years (JSR). Survival FU deaths: up to 4.3 years (Part 1), 5.1 years (Part 2) and 0.9 years (Part 3) and 0.9 years (JSR)

Notes:

[109] - 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: For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status

End point values	Part 1: RCC naïve 160 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N pre 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11[110]	14[111]	14[112]	12[113]
Units: participants				
On-treatment and post-treatment safety FU deaths	4	10	6	4
Survival FU deaths	3	3	4	4
All deaths	7	13	10	8

Notes:

[110] - n=11 (on-treatment and safety FU), 7 (survival FU), 11 (all)

[111] - n=14 (on-treatment and safety FU), 4 (survival FU), 14 (all)

[112] - n=14 (on-treatment and safety FU), 8 (survival FU), 14 (all)

[113] - n=12 (on-treatment and safety FU), 8 (survival FU), 12 (all)

End point values	Part 1: TNBC 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30[114]	13[115]	6[116]	15[117]
Units: participants				
On-treatment and post-treatment safety FU deaths	9	9	2	2
Survival FU deaths	12	2	3	7
All deaths	21	11	5	9

Notes:
[114] - n=30 (on-treatment and safety FU), 21 (survival FU), 30 (all)
[115] - n=13 (on-treatment and safety FU), 4 (survival FU), 13 (all)
[116] - n=6 (on-treatment and safety FU), 4 (survival FU), 6 (all)
[117] - n=15 (on-treatment and safety FU), 13 (survival FU), 15 (all)

End point values	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22[118]	20[119]	20[120]	6[121]
Units: participants				
On-treatment and post-treatment safety FU deaths	6	4	6	4
Survival FU deaths	8	9	7	1
All deaths	14	13	13	5

Notes:
[118] - n=22 (on-treatment and safety FU), 16 (survival FU), 22 (all)
[119] - n=20 (on-treatment and safety FU), 16 (survival FU), 20 (all)
[120] - n=20 (on-treatment and safety FU), 14 (survival FU), 20 (all)
[121] - n=6 (on-treatment and safety FU), 2 (survival FU), 6 (all)

End point values	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	Part 1: RCC naïve + pre 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3[122]	3[123]	3[124]	23[125]
Units: participants				
On-treatment and post-treatment safety FU deaths	2	0	1	6
Survival FU deaths	0	0	1	7
All deaths	2	0	2	13

Notes:
[122] - n=3 (on-treatment and safety FU), 0 (survival FU), 3 (all)
[123] - n=3 (on-treatment and safety FU), 0 (survival FU), 3 (all)
[124] - n=3 (on-treatment and safety FU), 1 (survival FU), 3 (all)
[125] - n=23 (on-treatment and safety FU), 17 (survival FU), 23 (all)

End point values	Part 1: H-N naïve + pre 160 mg	Part 1: MSS CRC 160 mg	Part 1: Melanoma naïve + pre 160 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	26[126]	58[127]	16[128]	
Units: participants				
On-treatment and post-treatment safety FU deaths	8	22	7	
Survival FU deaths	12	22	8	
All deaths	20	44	15	

Notes:
[126] - n=26 (on-treatment and safety FU), 18 (survival FU), 26 (all)
[127] - n=58 (on-treatment and safety FU), 36 (survival FU), 58 (all)
[128] - n=16 (on-treatment and safety FU), 9 (survival FU), 16 (all)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

AEs were collected from first dose of study treatment to 150 days after last dose of NIR178+PDR001, up to 4.3 years (Part 1), 5.1 years (Part 2), 0.9 years (Part 3) and 0.9 years (Japan safety run-in; JSR).

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Part 1: RCC naïve 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy

Reporting group title	Part 1: RCC naïve + pre 240 mg

Reporting group description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with immuno-oncology therapy

Reporting group title	Part 1: mCRPC 240 mg

Reporting group description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)

Reporting group title	Part 1: DLBCL 240 mg

Reporting group description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)

Reporting group title	Part 1: DLBCL 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)

Reporting group title	Part 1: Melanoma naïve + pre 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with immuno-oncology therapy

Reporting group title	Part 1: TNBC 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)

Reporting group title	Part 1: MSS CRC 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtype, RAS mutant and RAS unknown status

Reporting group title	Part 1: Pancreatic 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer

Reporting group title	Part 1: Urothelial 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer

Reporting group title	Part 1: H-N naïve + pre 160 mg

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and pretreated with immuno-oncology therapy

Reporting group title	Part 1: H-N pre 240 mg

Reporting group description:

NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy

Reporting group title	Part 2: NSCLC 160 mg 2wk-on/2wk-off

Reporting group description:

NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)

Reporting group title	Part 2: NSCLC 160 mg cont

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)

Reporting group title	JSR: 160 mg cont

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in

Reporting group title	JSR: 80 mg cont

Reporting group description:

NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in

Reporting group title	Part 3: TNBC 160 mg cont

Reporting group description:

NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)

Reporting group title	Part 2: NSCLC 160 mg 1wk-on/1wk-off

Reporting group description:

NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)

Reporting group title	JSR: 240 mg cont

Reporting group description:

NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in

Serious adverse events	Part 1: RCC naïve 160 mg	Part 1: RCC naïve + pre 240 mg	Part 1: mCRPC 240 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 11 (27.27%)	7 / 23 (30.43%)	5 / 15 (33.33%)
number of deaths (all causes)	4	6	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tumour thrombotic microangiopathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast			

disorders			
Female genital tract fistula			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peyronie's disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 11 (9.09%)	1 / 23 (4.35%)	0 / 15 (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
Haemoptysis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (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
Overdose			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune myocarditis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myocardial infarction			
subjects affected / exposed	1 / 11 (9.09%)	1 / 23 (4.35%)	0 / 15 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gaze palsy			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (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
Colonic fistula			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (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
Hepatic failure			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (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
Hepatic haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune myositis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain in extremity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacral pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (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
Peritonitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (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
Urinary tract infection			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital infection bacterial			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1: DLBCL 240 mg	Part 1: DLBCL 160 mg	Part 1: Melanoma naïve + pre 160 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	7 / 13 (53.85%)	4 / 16 (25.00%)
number of deaths (all causes)	2	9	7
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tumour thrombotic microangiopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Generalised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Female genital tract fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peyronie's disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune myocarditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (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
Eye disorders			
Blindness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gaze palsy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Autoimmune myositis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital infection bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1: TNBC 160 mg	Part 1: MSS CRC 160 mg	Part 1: Pancreatic 160 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 30 (46.67%)	28 / 58 (48.28%)	9 / 14 (64.29%)
number of deaths (all causes)	9	22	10
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastases to meninges			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tumour thrombotic microangiopathy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	1 / 30 (3.33%)	1 / 58 (1.72%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Chest pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (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
General physical health deterioration			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	2 / 14 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Generalised oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 30 (3.33%)	4 / 58 (6.90%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast			

disorders			
Female genital tract fistula			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peyronie's disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	2 / 30 (6.67%)	3 / 58 (5.17%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			

subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (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
Mediastinal disorder			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 30 (0.00%)	3 / 58 (5.17%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			

subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (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
Troponin I increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune myocarditis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myocardial infarction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (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
Paraesthesia			

subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gaze palsy			

subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (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
Constipation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (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
Dysphagia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 30 (0.00%)	3 / 58 (5.17%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune myositis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain in extremity			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacral pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pleural infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital infection bacterial			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (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
Hyperglycaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1: Urothelial 160 mg	Part 1: H-N naïve + pre 160 mg	Part 1: H-N pre 240 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 14 (50.00%)	16 / 26 (61.54%)	5 / 12 (41.67%)
number of deaths (all causes)	6	8	4
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tumour thrombotic microangiopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			

subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tumour pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (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
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical health deterioration			
subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Female genital tract fistula			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peyronie's disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (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
Respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (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
Blood creatinine increased			

subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (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
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune myocarditis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gaze palsy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			

subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Autoimmune myositis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacral pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	1 / 14 (7.14%)	3 / 26 (11.54%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Scrotal abscess			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 14 (14.29%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital infection bacterial			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg cont	JSR: 160 mg cont
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 20 (45.00%)	11 / 22 (50.00%)	1 / 3 (33.33%)
number of deaths (all causes)	4	6	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Metastases to central nervous system			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Metastases to meninges			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Neoplasm progression			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 tumour thrombotic microangiopathy			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	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
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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	1 / 20 (5.00%)	0 / 22 (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
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Chest pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Disease progression			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Face oedema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Fatigue			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (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
General physical health deterioration			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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 / 1	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Oedema peripheral			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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	0 / 20 (0.00%)	0 / 22 (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
Reproductive system and breast			

disorders			
Female genital tract fistula			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Peyronie's disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Cough			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Hydrothorax			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Interstitial lung disease			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Mediastinal disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 effusion			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	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
Pneumothorax			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	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
Pulmonary embolism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 haemorrhage			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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
Respiratory failure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Amylase increased			

subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 bilirubin increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 creatine phosphokinase increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 creatinine increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (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
General physical condition abnormal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Lipase increased			

subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (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
Troponin I increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Fall			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 injuries			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Overdose			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Atrial tachycardia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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 / 1	0 / 0	0 / 0
Autoimmune myocarditis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 / 20 (0.00%)	1 / 22 (4.55%)	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 / 1	0 / 0

Myocardial infarction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Pericardial effusion			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Cerebral infarction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Cerebrospinal fluid leakage			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (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
Migraine			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Paraesthesia			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 / 20 (0.00%)	0 / 22 (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
Spinal cord compression			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Syncope			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 / 20 (0.00%)	0 / 22 (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
Febrile neutropenia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 / 20 (0.00%)	0 / 22 (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			
Blindness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Gaze palsy			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Abdominal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Ascites			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Constipation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Colonic fistula			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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	0 / 20 (0.00%)	0 / 22 (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
Duodenal ulcer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Dysphagia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 / 20 (0.00%)	0 / 22 (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 / 20 (0.00%)	0 / 22 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 / 20 (5.00%)	0 / 22 (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
Pancreatitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 / 20 (0.00%)	0 / 22 (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 / 20 (0.00%)	1 / 22 (4.55%)	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
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Autoimmune hepatitis			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Cholecystitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Hepatic failure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Hepatic haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Hepatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Immune-mediated hepatitis			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Liver disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Erythema multiforme			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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
Rash			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Stevens-Johnson syndrome			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Haematuria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Nephrolithiasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 impairment			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Arthralgia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Autoimmune myositis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Back pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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	1 / 20 (5.00%)	0 / 22 (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
Flank pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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

Pain in extremity			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Sacral pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Bronchitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (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
Encephalitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Herpes zoster			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Influenza			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Large intestine infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Peritonitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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
Pleural infection			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (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
Pneumonia			
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Scrotal abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Sepsis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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	0 / 20 (0.00%)	0 / 22 (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
Urogenital infection bacterial			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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 device infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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			
Decreased appetite			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Hyperglycaemia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (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
Hypervolaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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
Hypokalaemia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (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
Hyponatraemia			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (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

Serious adverse events	JSR: 80 mg cont	Part 3: TNBC 160 mg cont	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	3 / 6 (50.00%)	7 / 20 (35.00%)
number of deaths (all causes)	2	4	6
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 tumour thrombotic microangiopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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			
Aortic aneurysm			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Female genital tract fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peyronie's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 20 (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
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	1 / 6 (16.67%)	3 / 20 (15.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 condition abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
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 injuries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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			
Atrial tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune myocarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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			
Blindness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gaze palsy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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			
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
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 impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Autoimmune myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 device infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
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	JSR: 240 mg cont		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Metastases to meninges				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neoplasm progression				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tumour thrombotic microangiopathy				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the tongue				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Aortic aneurysm				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Chest pain				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disease progression				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Face oedema				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised oedema				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Female genital tract fistula				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peyronie's disease				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Chronic obstructive pulmonary disease				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrothorax				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Interstitial lung disease				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mediastinal disorder				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Alanine aminotransferase increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Amylase increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspartate aminotransferase increased				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood bilirubin increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical condition abnormal				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lipase increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Troponin I increased				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune myocarditis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Supraventricular tachycardia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebral haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrospinal fluid leakage				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord compression			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Blindness			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gaze palsy			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Abdominal pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colonic fistula				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Autoimmune hepatitis				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic failure				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated hepatitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver disorder				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stevens-Johnson syndrome			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			

Adrenal insufficiency				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperthyroidism				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune myositis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Sacral pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis infectious				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine infection				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scrotal abscess				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urogenital infection bacterial				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular device infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Decreased appetite				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypervolaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Part 1: RCC naïve 160 mg	Part 1: RCC naïve + pre 240 mg	Part 1: mCRPC 240 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 11 (90.91%)	22 / 23 (95.65%)	14 / 15 (93.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neoplasm progression			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	2 / 15 (13.33%)
occurrences (all)	0	1	3
Raynaud's phenomenon			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site bruise			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	2 / 11 (18.18%)	5 / 23 (21.74%)	1 / 15 (6.67%)
occurrences (all)	3	5	1
Axillary pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 11 (36.36%)	5 / 23 (21.74%)	4 / 15 (26.67%)
occurrences (all)	4	5	4
Feeling of body temperature change			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	2 / 11 (18.18%)	2 / 23 (8.70%)	1 / 15 (6.67%)
occurrences (all)	2	2	1
Peripheral swelling			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 11 (9.09%)	2 / 23 (8.70%)	2 / 15 (13.33%)
occurrences (all)	1	3	2
Swelling face			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Balanoposthitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Breast oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Peyronie's disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	1 / 11 (9.09%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Dyspnoea exertional			
subjects affected / exposed	1 / 11 (9.09%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			
subjects affected / exposed	1 / 11 (9.09%)	1 / 23 (4.35%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Dysphonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	2 / 15 (13.33%)
occurrences (all)	0	3	2
Epistaxis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Rhinorrhoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sputum retention			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tonsillar erythema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Depression			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Mood altered			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Panic disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 11 (0.00%)	3 / 23 (13.04%)	2 / 15 (13.33%)
occurrences (all)	0	4	2
Restlessness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			

subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Stress			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 11 (18.18%)	2 / 23 (8.70%)	3 / 15 (20.00%)
occurrences (all)	2	3	3
Amylase increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	4 / 15 (26.67%)
occurrences (all)	1	0	6
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 11 (18.18%)	2 / 23 (8.70%)	3 / 15 (20.00%)
occurrences (all)	4	3	3
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	3
Eosinophil count increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 11 (9.09%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Haemoglobin decreased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	4 / 15 (26.67%)
occurrences (all)	1	0	7
Oxygen saturation decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test negative			
subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	1 / 15 (6.67%)
occurrences (all)	0	2	5
Transaminases increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Wound necrosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Bradycardia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Coronary artery disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Cardiac failure congestive			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	1 / 15 (6.67%)
occurrences (all)	0	5	3

Autonomic nervous system imbalance			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 11 (9.09%)	2 / 23 (8.70%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Headache			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	4	0	0
Paraesthesia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	2 / 15 (13.33%)
occurrences (all)	0	2	2
Leukocytosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Vertigo			

subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Eye disorders			
Cataract			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 11 (0.00%)	3 / 23 (13.04%)	0 / 15 (0.00%)
occurrences (all)	0	3	0
Abdominal pain upper			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 11 (9.09%)	2 / 23 (8.70%)	2 / 15 (13.33%)
occurrences (all)	1	2	2
Diarrhoea			
subjects affected / exposed	1 / 11 (9.09%)	8 / 23 (34.78%)	3 / 15 (20.00%)
occurrences (all)	1	9	3
Dental caries			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Constipation			

subjects affected / exposed	1 / 11 (9.09%)	7 / 23 (30.43%)	2 / 15 (13.33%)
occurrences (all)	1	7	2
Faeces soft			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	2 / 11 (18.18%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	3	0	1
Flatulence			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Dry mouth			
subjects affected / exposed	1 / 11 (9.09%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Ileus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	1 / 11 (9.09%)	5 / 23 (21.74%)	5 / 15 (33.33%)
occurrences (all)	1	6	5
Retching			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	0 / 15 (0.00%)
occurrences (all)	0	3	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypertransaminasaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			

subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Alopecia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
Eczema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	2 / 11 (18.18%)	5 / 23 (21.74%)	4 / 15 (26.67%)
occurrences (all)	3	5	4

Pruritus			
subjects affected / exposed	3 / 11 (27.27%)	2 / 23 (8.70%)	1 / 15 (6.67%)
occurrences (all)	4	2	1
Pemphigoid			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Vitiligo			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Azotaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Chronic kidney disease			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	1 / 15 (6.67%)
occurrences (all)	0	1	2
Haematuria			
subjects affected / exposed	1 / 11 (9.09%)	2 / 23 (8.70%)	1 / 15 (6.67%)
occurrences (all)	1	4	1
Leukocyturia			
subjects affected / exposed	2 / 11 (18.18%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Nocturia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Urinary retention			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Urethral pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Amyotrophy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	3 / 11 (27.27%)	2 / 23 (8.70%)	2 / 15 (13.33%)
occurrences (all)	3	2	2
Back pain			
subjects affected / exposed	3 / 11 (27.27%)	5 / 23 (21.74%)	3 / 15 (20.00%)
occurrences (all)	3	5	3
Bone pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Joint stiffness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Muscle atrophy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	1 / 15 (6.67%)
occurrences (all)	0	1	1

Muscular weakness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 23 (4.35%)	3 / 15 (20.00%)
occurrences (all)	1	1	3
Neck pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Osteoarthritis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Pain in jaw			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Device related infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
COVID-19			

subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Body tinea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 11 (18.18%)	1 / 23 (4.35%)	2 / 15 (13.33%)
occurrences (all)	2	1	2
Urogenital infection bacterial			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vaginal infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Decreased appetite			
subjects affected / exposed	1 / 11 (9.09%)	3 / 23 (13.04%)	2 / 15 (13.33%)
occurrences (all)	1	3	2
Dehydration			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 11 (9.09%)	3 / 23 (13.04%)	0 / 15 (0.00%)
occurrences (all)	1	4	0
Hyperuricaemia			
subjects affected / exposed	1 / 11 (9.09%)	2 / 23 (8.70%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Hyperlipasaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 23 (8.70%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
Hyperglycaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Hyponatraemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 23 (4.35%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Iron deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Tumour lysis syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 23 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1: DLBCL 240 mg	Part 1: DLBCL 160 mg	Part 1: Melanoma naïve + pre 160 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 6 (83.33%)	13 / 13 (100.00%)	14 / 16 (87.50%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic keratosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Lymphoedema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Administration site bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	4 / 16 (25.00%)
occurrences (all)	0	2	5
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	3 / 16 (18.75%)
occurrences (all)	0	1	3
Feeling of body temperature change			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	1 / 6 (16.67%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	4 / 13 (30.77%)	0 / 16 (0.00%)
occurrences (all)	1	4	0
Swelling face			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			

subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Breast oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Peyronie's disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Epistaxis			

subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Rhinalgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 6 (16.67%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Sputum retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tonsillar erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Mood altered			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Panic disorder			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	0	3	0
Restlessness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Stress			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)	2 / 13 (15.38%)	2 / 16 (12.50%)
occurrences (all)	1	2	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Blood phosphorus increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Eosinophil count increased			

subjects affected / exposed	1 / 6 (16.67%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Oxygen saturation decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test negative			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Wound complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Wound necrosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Extrasystoles			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Coronary artery disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Palpitations			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dysgeusia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	1 / 16 (6.25%)
occurrences (all)	0	1	2
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Taste disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	3	0
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	3 / 13 (23.08%)	3 / 16 (18.75%)
occurrences (all)	1	3	4
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	1 / 6 (16.67%)	3 / 13 (23.08%)	0 / 16 (0.00%)
occurrences (all)	1	7	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Dental caries			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 6 (16.67%)	3 / 13 (23.08%)	1 / 16 (6.25%)
occurrences (all)	1	3	1
Faeces soft			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0

Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	4 / 16 (25.00%)
occurrences (all)	0	3	4
Retching			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	1 / 6 (16.67%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	0	3	0
Hepatobiliary disorders			
Cholestasis			

subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	2	0

Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Hyperkeratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	1 / 16 (6.25%)
occurrences (all)	0	3	1
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	2 / 16 (12.50%)
occurrences (all)	0	1	2
Pemphigoid			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Scar pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Azotaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Leukocyturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Urinary retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Fracture pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Muscle atrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			

subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	3 / 16 (18.75%)
occurrences (all)	0	2	3
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Eye infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Oesophageal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Rash pustular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	0	2	0

Urinary tract infection enterococcal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Urogenital infection bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Decreased appetite			
subjects affected / exposed	0 / 6 (0.00%)	3 / 13 (23.08%)	2 / 16 (12.50%)
occurrences (all)	0	3	2
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Hyperlipasaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 13 (23.08%)	0 / 16 (0.00%)
occurrences (all)	0	5	0
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Obesity			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 16 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Part 1: TNBC 160 mg	Part 1: MSS CRC 160 mg	Part 1: Pancreatic 160 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 30 (96.67%)	52 / 58 (89.66%)	14 / 14 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neoplasm progression			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	2 / 30 (6.67%)	3 / 58 (5.17%)	0 / 14 (0.00%)
occurrences (all)	2	4	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hot flush			

subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Hypertension			
subjects affected / exposed	2 / 30 (6.67%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	3	4	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Superficial vein thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	3
General disorders and administration site conditions			
Administration site bruise			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	5 / 30 (16.67%)	3 / 58 (5.17%)	1 / 14 (7.14%)
occurrences (all)	7	3	1
Axillary pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 30 (3.33%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Discomfort			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 30 (6.67%)	4 / 58 (6.90%)	0 / 14 (0.00%)
occurrences (all)	2	4	0
Chest pain			
subjects affected / exposed	4 / 30 (13.33%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	5	2	0
Fatigue			
subjects affected / exposed	10 / 30 (33.33%)	20 / 58 (34.48%)	5 / 14 (35.71%)
occurrences (all)	11	21	5
Feeling of body temperature change			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
General physical health deterioration			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 30 (3.33%)	3 / 58 (5.17%)	0 / 14 (0.00%)
occurrences (all)	1	3	0
Oedema			
subjects affected / exposed	2 / 30 (6.67%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			

subjects affected / exposed	2 / 30 (6.67%)	5 / 58 (8.62%)	2 / 14 (14.29%)
occurrences (all)	2	6	3
Peripheral swelling			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	9 / 30 (30.00%)	9 / 58 (15.52%)	1 / 14 (7.14%)
occurrences (all)	12	14	5
Swelling face			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Breast oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peyronie's disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Breast pain			

subjects affected / exposed	2 / 30 (6.67%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Vaginal discharge			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	2 / 30 (6.67%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Dyspnoea			
subjects affected / exposed	6 / 30 (20.00%)	8 / 58 (13.79%)	2 / 14 (14.29%)
occurrences (all)	7	9	2
Dysphonia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	10 / 30 (33.33%)	11 / 58 (18.97%)	2 / 14 (14.29%)
occurrences (all)	12	13	2
Epistaxis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	1 / 30 (3.33%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Nasal congestion			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Haemoptysis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Productive cough			

subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Respiratory failure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Sputum retention			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tonsillar erythema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	3 / 30 (10.00%)	1 / 58 (1.72%)	1 / 14 (7.14%)
occurrences (all)	3	1	1
Depression			
subjects affected / exposed	0 / 30 (0.00%)	4 / 58 (6.90%)	1 / 14 (7.14%)
occurrences (all)	0	5	1
Mood altered			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Panic disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0

Insomnia			
subjects affected / exposed	1 / 30 (3.33%)	4 / 58 (6.90%)	2 / 14 (14.29%)
occurrences (all)	1	4	2
Restlessness			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Stress			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	9 / 30 (30.00%)	11 / 58 (18.97%)	0 / 14 (0.00%)
occurrences (all)	14	13	0
Amylase increased			
subjects affected / exposed	2 / 30 (6.67%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	9 / 30 (30.00%)	14 / 58 (24.14%)	1 / 14 (7.14%)
occurrences (all)	12	19	1
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 30 (10.00%)	3 / 58 (5.17%)	0 / 14 (0.00%)
occurrences (all)	3	3	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 30 (0.00%)	4 / 58 (6.90%)	1 / 14 (7.14%)
occurrences (all)	0	4	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 30 (0.00%)	4 / 58 (6.90%)	0 / 14 (0.00%)
occurrences (all)	0	4	0
Blood creatinine increased			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	1 / 30 (3.33%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Eosinophil count increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 30 (10.00%)	6 / 58 (10.34%)	0 / 14 (0.00%)
occurrences (all)	3	6	0
Haemoglobin decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	1 / 30 (3.33%)	4 / 58 (6.90%)	0 / 14 (0.00%)
occurrences (all)	1	4	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Platelet count decreased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
SARS-CoV-2 test negative			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 30 (3.33%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Fall			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Wound complication			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Wound necrosis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Coronary artery disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	1 / 14 (7.14%)
occurrences (all)	0	3	1
Pericardial effusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Tachycardia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Nervous system disorders			
Anosmia			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	4 / 30 (13.33%)	1 / 58 (1.72%)	5 / 14 (35.71%)
occurrences (all)	5	1	5
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	4 / 30 (13.33%)	3 / 58 (5.17%)	2 / 14 (14.29%)
occurrences (all)	4	3	2
Paraesthesia			
subjects affected / exposed	3 / 30 (10.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	4	2	0

Peripheral sensory neuropathy			
subjects affected / exposed	1 / 30 (3.33%)	1 / 58 (1.72%)	1 / 14 (7.14%)
occurrences (all)	1	1	1
Presyncope			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	1 / 30 (3.33%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Seizure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	4 / 30 (13.33%)	5 / 58 (8.62%)	3 / 14 (21.43%)
occurrences (all)	5	7	3
Leukocytosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neutropenia			

subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	1 / 30 (3.33%)	3 / 58 (5.17%)	0 / 14 (0.00%)
occurrences (all)	2	3	0
Abdominal pain upper			
subjects affected / exposed	0 / 30 (0.00%)	6 / 58 (10.34%)	2 / 14 (14.29%)
occurrences (all)	0	6	2
Abdominal pain			
subjects affected / exposed	2 / 30 (6.67%)	9 / 58 (15.52%)	4 / 14 (28.57%)
occurrences (all)	3	10	4
Diarrhoea			
subjects affected / exposed	3 / 30 (10.00%)	12 / 58 (20.69%)	0 / 14 (0.00%)
occurrences (all)	3	12	0
Dental caries			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 30 (0.00%)	4 / 58 (6.90%)	1 / 14 (7.14%)
occurrences (all)	0	5	1
Constipation			
subjects affected / exposed	2 / 30 (6.67%)	9 / 58 (15.52%)	1 / 14 (7.14%)
occurrences (all)	2	9	1
Faeces soft			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Dyspepsia			
subjects affected / exposed	2 / 30 (6.67%)	4 / 58 (6.90%)	0 / 14 (0.00%)
occurrences (all)	3	4	0
Flatulence			
subjects affected / exposed	1 / 30 (3.33%)	5 / 58 (8.62%)	0 / 14 (0.00%)
occurrences (all)	1	5	0
Dry mouth			
subjects affected / exposed	2 / 30 (6.67%)	2 / 58 (3.45%)	1 / 14 (7.14%)
occurrences (all)	2	2	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Ileus			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	9 / 30 (30.00%)	13 / 58 (22.41%)	4 / 14 (28.57%)
occurrences (all)	13	16	4
Retching			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 30 (3.33%)	3 / 58 (5.17%)	1 / 14 (7.14%)
occurrences (all)	1	3	1
Toothache			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	5 / 30 (16.67%)	12 / 58 (20.69%)	3 / 14 (21.43%)
occurrences (all)	5	17	3
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hepatic failure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Jaundice			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Immune-mediated hepatitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 30 (3.33%)	3 / 58 (5.17%)	0 / 14 (0.00%)
occurrences (all)	1	3	0
Eczema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Intertrigo			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			

subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Rash			
subjects affected / exposed	1 / 30 (3.33%)	3 / 58 (5.17%)	0 / 14 (0.00%)
occurrences (all)	1	3	0
Pruritus			
subjects affected / exposed	3 / 30 (10.00%)	8 / 58 (13.79%)	0 / 14 (0.00%)
occurrences (all)	4	10	0
Pemphigoid			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Scar pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Vitiligo			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Azotaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Bladder pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Nocturia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Urethral pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 30 (3.33%)	2 / 58 (3.45%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Hypothyroidism			
subjects affected / exposed	3 / 30 (10.00%)	5 / 58 (8.62%)	1 / 14 (7.14%)
occurrences (all)	3	5	1
Lymphocytic hypophysitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	8 / 30 (26.67%)	9 / 58 (15.52%)	3 / 14 (21.43%)
occurrences (all)	9	12	3
Back pain			
subjects affected / exposed	4 / 30 (13.33%)	5 / 58 (8.62%)	1 / 14 (7.14%)
occurrences (all)	4	6	1
Bone pain			
subjects affected / exposed	0 / 30 (0.00%)	2 / 58 (3.45%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Flank pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Fracture pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Muscle atrophy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			

subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	3 / 30 (10.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Muscular weakness			
subjects affected / exposed	1 / 30 (3.33%)	5 / 58 (8.62%)	1 / 14 (7.14%)
occurrences (all)	1	5	1
Muscle spasms			
subjects affected / exposed	1 / 30 (3.33%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Myalgia			
subjects affected / exposed	4 / 30 (13.33%)	4 / 58 (6.90%)	0 / 14 (0.00%)
occurrences (all)	4	5	0
Neck pain			
subjects affected / exposed	2 / 30 (6.67%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Osteoarthritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Pain in jaw			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Trismus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Device related infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	2 / 30 (6.67%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Eye infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	2 / 30 (6.67%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 58 (1.72%)	1 / 14 (7.14%)
occurrences (all)	1	1	1
Oesophageal candidiasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1

Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 58 (1.72%)	1 / 14 (7.14%)
occurrences (all)	1	1	1
Tracheitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 30 (10.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	4	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 30 (6.67%)	5 / 58 (8.62%)	2 / 14 (14.29%)
occurrences (all)	4	7	2
Urogenital infection bacterial			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0

Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	4 / 30 (13.33%)	17 / 58 (29.31%)	7 / 14 (50.00%)
occurrences (all)	4	21	7
Dehydration			
subjects affected / exposed	0 / 30 (0.00%)	3 / 58 (5.17%)	1 / 14 (7.14%)
occurrences (all)	0	3	1
Glucose tolerance impaired			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 58 (1.72%)	2 / 14 (14.29%)
occurrences (all)	2	1	2
Hypoalbuminaemia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypokalaemia			

subjects affected / exposed	3 / 30 (10.00%)	4 / 58 (6.90%)	3 / 14 (21.43%)
occurrences (all)	4	6	6
Hypomagnesaemia			
subjects affected / exposed	3 / 30 (10.00%)	1 / 58 (1.72%)	2 / 14 (14.29%)
occurrences (all)	3	1	2
Hyponatraemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	1 / 30 (3.33%)	3 / 58 (5.17%)	0 / 14 (0.00%)
occurrences (all)	1	3	0
Iron deficiency			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 30 (0.00%)	1 / 58 (1.72%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Obesity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 30 (3.33%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 58 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1: Urothelial 160 mg	Part 1: H-N naïve + pre 160 mg	Part 1: H-N pre 240 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)	25 / 26 (96.15%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Neoplasm progression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	2 / 14 (14.29%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	2
Superficial vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site bruise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Axillary pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 14 (0.00%)	3 / 26 (11.54%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
Chills			
subjects affected / exposed	1 / 14 (7.14%)	3 / 26 (11.54%)	0 / 12 (0.00%)
occurrences (all)	1	3	0
Chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	2 / 14 (14.29%)	11 / 26 (42.31%)	3 / 12 (25.00%)
occurrences (all)	2	13	3
Feeling of body temperature change			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	3 / 14 (21.43%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	3	3	0
Peripheral swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	4 / 14 (28.57%)	4 / 26 (15.38%)	0 / 12 (0.00%)
occurrences (all)	7	5	0
Swelling face			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peyronie's disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pelvic pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	4 / 14 (28.57%)	2 / 26 (7.69%)	1 / 12 (8.33%)
occurrences (all)	4	2	1
Dysphonia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	4 / 14 (28.57%)	4 / 26 (15.38%)	0 / 12 (0.00%)
occurrences (all)	6	5	0
Epistaxis			
subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Pleural effusion			
subjects affected / exposed	2 / 14 (14.29%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Nasal congestion			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sputum retention			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tonsillar erythema			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Panic disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Restlessness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	2 / 14 (14.29%)	3 / 26 (11.54%)	1 / 12 (8.33%)
occurrences (all)	2	3	2
Amylase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 14 (14.29%)	3 / 26 (11.54%)	1 / 12 (8.33%)
occurrences (all)	2	3	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Bilirubin conjugated increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	1 / 12 (8.33%)
occurrences (all)	1	1	2
Blood creatinine increased			
subjects affected / exposed	3 / 14 (21.43%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
C-reactive protein increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Eosinophil count increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oxygen saturation decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
SARS-CoV-2 test negative			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound necrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Bradycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Coronary artery disease			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pericardial effusion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Sinus tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Anosmia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Amnesia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	2 / 14 (14.29%)	1 / 26 (3.85%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphasia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dysaesthesia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
Paraesthesia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Somnolence			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	5 / 14 (35.71%)	5 / 26 (19.23%)	0 / 12 (0.00%)
occurrences (all)	5	5	0
Leukocytosis			
subjects affected / exposed	2 / 14 (14.29%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Lymphadenitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Eye disorders			
Cataract			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Photopsia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 14 (14.29%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 14 (7.14%)	3 / 26 (11.54%)	0 / 12 (0.00%)
occurrences (all)	1	3	0
Diarrhoea			
subjects affected / exposed	4 / 14 (28.57%)	4 / 26 (15.38%)	1 / 12 (8.33%)
occurrences (all)	9	8	1
Dental caries			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 14 (14.29%)	4 / 26 (15.38%)	1 / 12 (8.33%)
occurrences (all)	3	4	1
Faeces soft			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	1 / 14 (7.14%)	4 / 26 (15.38%)	0 / 12 (0.00%)
occurrences (all)	1	4	0

Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	1 / 14 (7.14%)	5 / 26 (19.23%)	1 / 12 (8.33%)
occurrences (all)	1	5	1
Dry mouth			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	5 / 14 (35.71%)	6 / 26 (23.08%)	2 / 12 (16.67%)
occurrences (all)	7	6	3
Retching			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 14 (7.14%)	3 / 26 (11.54%)	0 / 12 (0.00%)
occurrences (all)	1	4	0
Toothache			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Vomiting			
subjects affected / exposed	3 / 14 (21.43%)	4 / 26 (15.38%)	0 / 12 (0.00%)
occurrences (all)	5	6	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Jaundice			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Eczema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Intertrigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	2 / 14 (14.29%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	3	2	0
Rash			
subjects affected / exposed	2 / 14 (14.29%)	3 / 26 (11.54%)	1 / 12 (8.33%)
occurrences (all)	2	4	1
Pruritus			
subjects affected / exposed	1 / 14 (7.14%)	2 / 26 (7.69%)	1 / 12 (8.33%)
occurrences (all)	2	2	1
Pemphigoid			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vitiligo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Azotaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Bladder pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	2 / 14 (14.29%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Leukocyturia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	4 / 26 (15.38%)	0 / 12 (0.00%)
occurrences (all)	0	5	0
Back pain			
subjects affected / exposed	3 / 14 (21.43%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	3	2	0
Bone pain			

subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Mobility decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Muscle atrophy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	2 / 12 (16.67%)
occurrences (all)	0	2	2
Neck pain			

subjects affected / exposed	0 / 14 (0.00%)	3 / 26 (11.54%)	1 / 12 (8.33%)
occurrences (all)	0	3	1
Osteoarthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	2 / 14 (14.29%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Pain in jaw			
subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Trismus			
subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	2	1	0

Herpes zoster			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Pharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Tracheitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Rash pustular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 14 (14.29%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Urinary tract infection enterococcal			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Urogenital infection bacterial			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	5 / 14 (35.71%)	6 / 26 (23.08%)	0 / 12 (0.00%)
occurrences (all)	5	8	0
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			

subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	3 / 14 (21.43%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Hypophosphataemia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 26 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Iron deficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Malnutrition			

subjects affected / exposed	0 / 14 (0.00%)	1 / 26 (3.85%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Obesity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 14 (7.14%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 26 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg cont	JSR: 160 mg cont
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 20 (80.00%)	22 / 22 (100.00%)	2 / 3 (66.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neoplasm progression			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site bruise			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Axillary pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	2 / 20 (10.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Discomfort			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Fatigue			
subjects affected / exposed	6 / 20 (30.00%)	11 / 22 (50.00%)	0 / 3 (0.00%)
occurrences (all)	6	12	0
Feeling of body temperature change			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oedema			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Peripheral swelling			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	4 / 20 (20.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Pyrexia			
subjects affected / exposed	4 / 20 (20.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	5	3	0
Swelling face			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast oedema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peyronie's disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	2 / 20 (10.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Dyspnoea			
subjects affected / exposed	1 / 20 (5.00%)	5 / 22 (22.73%)	0 / 3 (0.00%)
occurrences (all)	1	5	0
Dysphonia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	2 / 20 (10.00%)	6 / 22 (27.27%)	1 / 3 (33.33%)
occurrences (all)	2	6	1
Epistaxis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Nasal congestion			

subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	4 / 20 (20.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	4	1	0
Productive cough			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Respiratory failure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 20 (0.00%)	3 / 22 (13.64%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Sputum retention			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tonsillar erythema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Mood altered			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Panic disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	3 / 20 (15.00%)	3 / 22 (13.64%)	0 / 3 (0.00%)
occurrences (all)	3	3	0
Restlessness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 20 (20.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	4	3	0
Amylase increased			
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 20 (20.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	4	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 20 (15.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 20 (20.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	2 / 20 (10.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test negative			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound necrosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Coronary artery disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Tachycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Headache			

subjects affected / exposed	2 / 20 (10.00%)	4 / 22 (18.18%)	0 / 3 (0.00%)
occurrences (all)	2	4	0
Paraesthesia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Presyncope			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	3 / 20 (15.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Leukocytosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lymphadenitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Photopsia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	3 / 20 (15.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	3	2	0
Abdominal pain upper			
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Abdominal pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			

subjects affected / exposed	1 / 20 (5.00%)	4 / 22 (18.18%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Dental caries			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	3 / 20 (15.00%)	8 / 22 (36.36%)	1 / 3 (33.33%)
occurrences (all)	4	11	1
Faeces soft			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	2 / 20 (10.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Flatulence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ileus			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 20 (15.00%)	5 / 22 (22.73%)	0 / 3 (0.00%)
occurrences (all)	4	6	0
Retching			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 20 (15.00%)	5 / 22 (22.73%)	0 / 3 (0.00%)
occurrences (all)	4	5	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Jaundice			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Eczema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hyperkeratosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Intertrigo			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Rash			
subjects affected / exposed	2 / 20 (10.00%)	3 / 22 (13.64%)	0 / 3 (0.00%)
occurrences (all)	3	3	0
Pruritus			
subjects affected / exposed	2 / 20 (10.00%)	5 / 22 (22.73%)	0 / 3 (0.00%)
occurrences (all)	2	6	0
Pemphigoid			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	2 / 20 (10.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Skin lesion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Azotaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Urinary retention			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hyperthyroidism			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			

subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	3 / 20 (15.00%)	3 / 22 (13.64%)	0 / 3 (0.00%)
occurrences (all)	3	3	0
Back pain			
subjects affected / exposed	3 / 20 (15.00%)	3 / 22 (13.64%)	0 / 3 (0.00%)
occurrences (all)	4	4	0
Bone pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Fracture pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Muscular weakness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Myalgia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Neck pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Pain in jaw			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Diarrhoea infectious			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Body tinea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Oral candidiasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 20 (0.00%)	3 / 22 (13.64%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Tracheitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urogenital infection bacterial			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Viral infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	5 / 20 (25.00%)	6 / 22 (27.27%)	0 / 3 (0.00%)
occurrences (all)	5	8	0
Dehydration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 20 (0.00%)	3 / 22 (13.64%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Hyperuricaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			

subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	3 / 20 (15.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	6	1	0
Hypomagnesaemia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hyponatraemia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	JSR: 80 mg cont	Part 3: TNBC 160 mg cont	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	17 / 20 (85.00%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Raynaud's phenomenon			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hypotension			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Superficial vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Catheter site oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	3 / 20 (15.00%)
occurrences (all)	0	1	4
Fatigue			

subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	5 / 20 (25.00%)
occurrences (all)	1	3	6
Feeling of body temperature change			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	4 / 20 (20.00%)
occurrences (all)	0	0	4
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	3
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Swelling face			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Breast oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Peyronie's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Intermenstrual bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Vaginal discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	5 / 20 (25.00%)
occurrences (all)	1	1	5
Dysphonia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	3 / 20 (15.00%)
occurrences (all)	1	0	4
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	2 / 20 (10.00%)
occurrences (all)	1	1	3
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sputum retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tonsillar erythema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Panic disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	5
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	3
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Blood phosphorus increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Oxygen saturation decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 3 (66.67%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test negative			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Wound necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Extrasystoles			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Coronary artery disease			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Aphasia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Lymphadenitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Photopsia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	3 / 6 (50.00%)	2 / 20 (10.00%)
occurrences (all)	0	3	6
Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	8 / 20 (40.00%)
occurrences (all)	0	2	9
Faeces soft			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Gastrointestinal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	4 / 6 (66.67%)	3 / 20 (15.00%)
occurrences (all)	1	6	3
Retching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	4 / 20 (20.00%)
occurrences (all)	1	2	5
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
Pemphigoid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Azotaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Leukocyturia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Urethral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	3
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 20 (5.00%)
occurrences (all)	0	4	1
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	3
Bone pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Fracture pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	3
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Neck pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 20 (10.00%)
occurrences (all)	0	1	3
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Body tinea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	4 / 20 (20.00%)
occurrences (all)	0	0	4
Tracheitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Rash pustular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Urogenital infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	3 / 20 (15.00%)
occurrences (all)	0	1	3
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Malnutrition			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	JSR: 240 mg cont		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Seborrhoeic keratosis			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Flushing			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Raynaud's phenomenon			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Superficial vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Administration site bruise			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Catheter site oedema			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Chest discomfort				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Discomfort				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Face oedema				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Chills				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Chest pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Fatigue				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Feeling of body temperature change				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Gait disturbance				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
General physical health deterioration				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Influenza like illness				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Malaise				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Oedema				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Balanoposthitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Breast oedema			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Peyronie's disease			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pelvic pain			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Intermenstrual bleeding				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Breast pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Vaginal discharge				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Respiratory, thoracic and mediastinal disorders				
Dyspnoea exertional				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Dyspnoea				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Dysphonia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Cough				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Epistaxis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pleural effusion				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Oropharyngeal pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Nasal congestion				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Rhinalgia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Sputum retention			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Tonsillar erythema			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Mood altered			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Panic disorder				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hallucination				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Insomnia				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Restlessness				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Sleep disorder				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Stress				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Investigations				
Alanine aminotransferase increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Amylase increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Aspartate aminotransferase increased				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Blood alkaline phosphatase increased				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Bilirubin conjugated increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood bilirubin increased				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood thyroid stimulating hormone increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood creatinine increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood lactate dehydrogenase increased				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Blood phosphorus increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
C-reactive protein increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Eosinophil count increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Haemoglobin decreased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
International normalised ratio increased				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Human chorionic gonadotropin increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Oxygen saturation decreased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
SARS-CoV-2 test negative			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Fall			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Wound complication			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Wound necrosis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Extrasystoles			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Coronary artery disease			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cardiac failure congestive			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Amnesia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Headache			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Seizure			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Lymphadenitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Diarrhoea			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Dental caries				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Ascites				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Faeces soft				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Flatulence				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Dry mouth				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Gastrointestinal disorder				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	2			
Haematochezia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Ileus				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Retching			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hepatic steatosis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypertransaminasaemia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Jaundice			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Immune-mediated hepatitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hyperkeratosis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Intertrigo			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pemphigoid			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Scar pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Vitiligo			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Azotaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Bladder pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Chronic kidney disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Dysuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Haematuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Leukocyturia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Nocturia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Urinary retention subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Urethral pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Hypothyroidism			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Fracture pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Mobility decreased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Joint stiffness			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Muscle atrophy			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Trismus			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Diarrhoea infectious				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Device related infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
COVID-19				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Body tinea				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Escherichia sepsis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Herpes zoster				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Eye infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Oesophageal candidiasis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

Oral candidiasis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Tracheitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Tinea versicolour				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Rash pustular				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Urinary tract infection enterococcal				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Urinary tract infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Urogenital infection bacterial				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Vaginal infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

Viral infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Metabolism and nutrition disorders				
Cachexia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Decreased appetite				
subjects affected / exposed	2 / 3 (66.67%)			
occurrences (all)	2			
Dehydration				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Glucose tolerance impaired				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hypercalcaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hyperuricaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hyperlipasaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hyperkalaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hyperglycaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hypoalbuminaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hypocalcaemia				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Obesity			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Vitamin B12 deficiency			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Tumour lysis syndrome			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 May 2017	• Updated inclusion criteria to require specific prior standard therapies for tumor types in Part 1. • Added exclusion criteria for patients with a history of non-infectious pneumonitis or interstitial lung disease (ILD). • Added inclusion criteria to ensure that the enrollment of patients with DLBCL was limited to patients with no available therapies of proven clinical benefit. • Provided case definitions for treatment-emergent immune-mediated ADRs in the protocol and guidance on assessment and management of immune-related AEs. • Included specific criteria for continuing study treatment beyond RECIST-defined radiological progression. • Updated risk-benefit section to indicate potential for overlapping toxicities of combination immunotherapies. • Clarified that the primary efficacy analysis was based on RECIST v1.1 for solid tumors and Cheson et al 2014 for lymphoma and that irRC criteria were used only for decisions around treatment discontinuation due to disease progression.
29 August 2017	• Included Japanese patients via separate safety run-in part to evaluate safety and PK properties of NIR178 as a single agent prior to their participation in different parts of the study. • Added Overall Response assessment by iRECIST as a secondary endpoint. • irRC criteria was replaced by iRECIST criteria for guiding decisions regarding treatment duration and/or discontinuation due to disease progression. • First dose reduction step from 160 mg (dose level -1) was changed from 80 mg to 120 mg BID after addition of a new NIR178 capsule strength (40 mg). • On-treatment biopsy and blood sample collection timepoint was moved from C3D15 ± 15 days and C2D1, respectively, to C2D1 +15 days to account for patients who could not obtain biopsies in Cycle 3 due to early disease progression or early response.
02 July 2018	• Incorporated language requiring study treatment discontinuation in the event of Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) in response to the occurrence of a case of Stevens Johnson Syndrome in the study. • Criteria for dose reduction/interruption and re-initiation of treatment for ADRs were updated to include latest toxicity management guidelines per American Society of Clinical Oncology (ASCO), National comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO). Moreover, the AST and ALT exclusion criteria was revised to align with the updated toxicity management guidelines.

29 October 2018	• Updated the protocol eligibility criteria and related statistical analysis sections for selected Part 1 indications based on preliminary evidence of anti-tumor activity and changes to the standard of care: • MSS CRC: In order to evaluate efficacy and safety in patients with different RAS genotypes, enrollment continued in two sub-groups (RAS wild-type & RAS mutant) based on locally available laboratory data. RAS status was collected, including for patients that were already enrolled. • Head & Neck: Enrollment was restricted to squamous cell carcinoma of the head and neck (HNSCC) to create a more homogenous patient population. In addition, a new treatment group (IO-pretreated HNSCC) was added. • Melanoma: Only cutaneous melanoma patients were to be enrolled. In addition, a new treatment group (IO-pretreated melanoma) was added, and the inclusion criteria was amended to require that BRAF V600 mutant patients be treated with prior BRAF V600 inhibitor therapy. • Scan assessments post discontinuation of study treatment no longer collected once the patient started a new antineoplastic therapy. • Added an optional biopsy for patients that continued study treatment beyond disease progression due to overall clinical benefit. • Removed blood sample collection for the assessment of serum cytokines used for retrospective analysis of a cytokine release syndrome AE.
28 November 2019	• Increased the dose of NIR178 to 240 mg BID from 160 mg BID for all newly enrolled patients based on emerging data. • Added two new treatment groups (mCRPC and IO-pretreated RCC) in Part 1. • Design of Part 3 was modified to allow for further evaluation of one or two tumor groups (from Parts 1 and 2). • Removed on-treatment plasma cfDNA biomarker sample collection and added an end of treatment cfDNA sample.
22 October 2020	• Opened Part 3 of the study to explore PDR001 + NIR178 in TNBC patients whose disease did not express PD-L1 IC=0 (<1%). • Introduced a new film-coated tablet (FCT) formulation of NIR178 into Part 3 of the study. • Reduced the ECG collection plan to safety monitoring levels. • Amended the safety run-in to assess NIR178 240 mg BID in combination with PDR001 400 mg Q4W starting at Cycle 1 in Japanese patients. • Revised the definition of end of study to include the option for patients deriving clinical benefit to transfer to another study or to an alternative treatment option. • Added drug-induced liver injury (DILI), autoimmune hepatitis, and pneumonitis follow-up guidance based on a Health Authority request.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
20 April 2018	The FDA placed study CNIR178X2201 on partial clinical hold (no new enrolment) on 20-Apr-2018 due to safety concerns related to immune related skin toxicities. Novartis voluntarily extended the temporary recruitment hold to non-US countries for CNIR178X2201. Ongoing patients could continue to receive the study drug per protocol, as long as they re-consented to participate. The FDA lifted the hold on 22-Jun-2018 after updates were made to the protocol amendment, ICF, and IB.	22 June 2018
02 November 2021	Novartis communicated to investigators the decision to halt further recruitment in the CNIR178X2201 study for business reasons based on the review of available study data.	-

Notes:

Limitations and caveats

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

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com for complete trial results.

Notes: