Clinical trial results:
An open label, Phase Ia/Ib dose finding study with BI 894999 orally administered once a day in patients with advanced malignancies with repeated administration in patients with clinical benefit

Summary

EudraCT number	2015-001111-12
Trial protocol	BE DE DK
Global end of trial date	23 November 2021

Results information

Result version number	v2 (current)
This version publication date	30 May 2024
First version publication date	15 December 2022
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	1367.1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02516553
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, 55216
Public contact	Boehringer Ingelheim, Call Center, Boehringer Ingelheim, 001 18002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	Boehringer Ingelheim, Call Center, Boehringer Ingelheim, 001 18002430127, clintriage.rdg@boehringer-ingelheim.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	31 January 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 November 2021
Global end of trial reached?	Yes
Global end of trial date	23 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The trial comprised a dose escalation phase (Phase Ia) and an expansion phase (Phase Ib). The main objective of this trial part was to determine the maximum tolerated dose (MTD) of BI 894999 monotherapy in patients with advanced and/or metastatic solid tumours in different dosing schedules in 3- or 4-week cycles (Schedule A with continuous dosing, Schedule B, with intermittent dosing [2 weeks on treatment, 1 week off treatment in 3-week cycles]; Schedule C, with intermittent dosing [a loading dose on first day followed by a maintenance dose for the next 6 days and followed by 1 week off treatment, repeated every 2 weeks in 4-week cycles]).

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were to be entered in the study. All subjects were free to withdraw from the clinical trial at any time for any reason given. If a subject continued to take trial medication, close monitoring was adhered to and all adverse events recorded. Rules were implemented in all trials whereby doses would be reduced if required. Thereafter, if further events were reported, the subject would be withdrawn from the trial. Symptomatic treatment of tumour associated symptoms were allowed throughout.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 July 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 137
Country: Number of subjects enrolled	France: 42
Country: Number of subjects enrolled	Germany: 19
Country: Number of subjects enrolled	Korea, Republic of: 1
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	United States: 28
Worldwide total number of subjects	231
EEA total number of subjects	202

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)	138
From 65 to 84 years	88
85 years and over	5

Subject disposition

Recruitment

Recruitment details:

This was an open label, Phase Ia/Ib dose finding study with BI 894999 orally administered once a day in patients with advanced malignancies with repeated administration in patients with clinical benefit.

Pre-assignment

Screening details:

For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg . For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.

Period 1

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

Blinding implementation details:

This was an open-label trial.

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase Ia - Schedule A: 0.2 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 0.2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 0.2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm title	Phase Ia - Schedule A: 0.5 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 0.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 0.5 milligram (mg) of BI 894999 once daily, in the morning, after an

overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm title	Phase Ia - Schedule A: 1 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 1 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm title	Phase Ia - Schedule A: 1.5 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm title	Phase Ia - Schedule A: 2 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a

continuous daily intake in cycles of 21 days.

Arm title	Phase Ia - Schedule A: 5 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Arm title	Phase Ia - Schedule B: 1.5 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm title	Phase Ia - Schedule B: 2 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm title	Phase Ia - Schedule B: 2.5 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2.5 mg of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm title	Phase Ia - Schedule C: 5/2.5 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm title	Phase Ia - Schedule C: 6/3 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm type	Experimental

Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm title	Phase Ia - Schedule C: 7/3.5 mg BI 894999

Arm description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 7 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 7 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm title	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)

Arm description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm title	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)

Arm description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm type	Experimental

Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm title	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)

Arm description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Arm title	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)

Arm description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 4 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 4 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm title	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)

Arm description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm type	Experimental

Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Arm title	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (SCLC patients)

Arm description:

This arm included adult patients diagnosed with small cell lung cancer (SCLC).
SCLC patients were initially administered 2.5 mg of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).
The Data Monitoring Committee decided on 28 November 2018 to lower the 2.5 mg BI 894999 dose due to safety concerns to 2mg, therefore patients treated before the decision were administered 2.5mg, and patients treated after the decision were administered 2mg.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Some of the patients of this arm were administered orally 2 milligram (mg) of BI 894999. The rest of the patients in this arm were administered 2.5 mg of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).

Arm title	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)

Arm description:

Adult patients diagnosed with colorectal cancer (CRC) were administered orally 2.5 milligram (mg) of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 2.5 milligram (mg) of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).

Arm title	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)

Arm description:

This arm included adult patients diagnosed with metastatic castrate resistant prostate cancer (mCRPC).
MCRPC patients were initialy administered 2.5 mg of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).
The Data Monitoring Committee decided on 28 November 2018 to lower the 2.5 mg BI 894999 dose due

to safety concerns to 2mg, therefore patients treated before the decision were administered 2.5mg, and patients treated after the decision were administered 2mg.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Some of the patients of this arm were administered orally 2 milligram (mg) of BI 894999 once daily. The rest of the patients in this arm were administered orally 2.5 mg of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).

Arm title	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)

Arm description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days. The 2.5 mg dose could be reduced to 2 mg in case of adverse events.

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days. The 2.5 mg dose could be reduced to 2 mg in case of adverse events.

Arm title	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)

Arm description:

This arm included adult patients diagnosed with NUT carcinoma (NC).
The DMC reclaimed the maximum tolerated dose (MTD) as 6/3mg on 08 July 2020 after 1 patient was already treated with 7/3.5mg, so the first patient in NC and all the following patients were treated with 6/3mg.
Patients in were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C).

Arm type	Experimental
Investigational medicinal product name	BI 894999
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Some of the patients in this arm were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The rest of the patients in this arm were administered orally once daily on Day 1 of each cycle a loading dose of 7 mg of BI 894999, followed by six days intake of the maintenance dose of 3.5 mg of BI 894999 once daily according to Schedule C.

Number of subjects in period 1[1]	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 0.5 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999
Started	2	2	3
Completed	0	0	0
Not completed	2	2	3
Dose limiting toxicity (DLTs)	-	-	-
Other Adverse Events	-	-	-
other reasons than listed	-	-	-
Progressive disease	2	2	3
Refused to continue trial medication	-	-	-

Number of subjects in period 1[1]	Phase Ia - Schedule A: 1.5 mg BI 894999	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule A: 5 mg BI 894999
Started	6	6	2
Completed	0	0	0
Not completed	6	6	2
Dose limiting toxicity (DLTs)	-	3	1
Other Adverse Events	1	-	1
other reasons than listed	-	-	-
Progressive disease	5	3	-
Refused to continue trial medication	-	-	-

Number of subjects in period 1[1]	Phase Ia - Schedule B: 1.5 mg BI 894999	Phase Ia - Schedule B: 2 mg BI 894999	Phase Ia - Schedule B: 2.5 mg BI 894999
Started	6	6	13
Completed	0	0	0
Not completed	6	6	13
Dose limiting toxicity (DLTs)	1	-	1
Other Adverse Events	-	-	-
other reasons than listed	-	1	1
Progressive disease	5	5	11
Refused to continue trial medication	-	-	-

Number of subjects in period 1[1]	Phase Ia - Schedule C: 5/2.5 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Started	4	15	12
Completed	0	0	0
Not completed	4	15	12
Dose limiting toxicity (DLTs)	-	-	1
Other Adverse Events	1	3	2
other reasons than listed	-	1	1
Progressive disease	3	10	8
Refused to continue trial medication	-	1	-

Number of subjects in period 1[1]	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)
Started	8	4	2
Completed	0	0	0
Not completed	8	4	2
Dose limiting toxicity (DLTs)	-	1	-
Other Adverse Events	-	1	-
other reasons than listed	-	-	-
Progressive disease	8	2	2
Refused to continue trial medication	-	-	-

Number of subjects in period 1[1]	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (SCLC patients)
Started	2	2	12
Completed	0	0	0
Not completed	2	2	12
Dose limiting toxicity (DLTs)	-	1	1
Other Adverse Events	-	-	2
other reasons than listed	-	-	-
Progressive disease	2	1	9
Refused to continue trial medication	-	-	-

Number of subjects in period 1[1]	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)
Started	14	11	20
Completed	0	0	0
Not completed	14	11	20
Dose limiting toxicity (DLTs)	-	2	-
Other Adverse Events	1	2	2
other reasons than listed	-	-	2
Progressive disease	12	7	16
Refused to continue trial medication	1	-	-

Number of subjects in period 1[1]	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)
Started	22
Completed	0
Not completed	22
Dose limiting toxicity (DLTs)	-
Other Adverse Events	1
other reasons than listed	2

Progressive disease	18
Refused to continue trial medication	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Out of 231 enrolled patients only 174 entered the trial.

Reporting groups

Reporting group title	Phase Ia - Schedule A: 0.2 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 0.2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 0.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 0.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 1 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 1.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 2 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 1.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in

cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2.5 mg of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule C: 5/2.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule C: 6/3 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule C: 7/3.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 7 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 4 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (SCLC patients)

Reporting group description:

This arm included adult patients diagnosed with small cell lung cancer (SCLC).
SCLC patients were initially administered 2.5 mg of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).
The Data Monitoring Committee decided on 28 November 2018 to lower the 2.5 mg BI 894999 dose due to safety concerns to 2mg, therefore patients treated before the decision were administered 2.5mg, and patients treated after the decision were administered 2mg.

Reporting group title	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)

Reporting group description:

Adult patients diagnosed with colorectal cancer (CRC) were administered orally 2.5 milligram (mg) of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).

Reporting group title	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)

Reporting group description:

This arm included adult patients diagnosed with metastatic castrate resistant prostate cancer (mCRPC).
MCRPC patients were initialy administered 2.5 mg of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).
The Data Monitoring Committee decided on 28 November 2018 to lower the 2.5 mg BI 894999 dose due to safety concerns to 2mg, therefore patients treated before the decision were administered 2.5mg, and patients treated after the decision were administered 2mg.

Reporting group title	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)

Reporting group description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days. The 2.5 mg dose could be reduced to 2 mg in case of adverse events.

Reporting group title	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)

Reporting group description:

This arm included adult patients diagnosed with NUT carcinoma (NC).
The DMC reclaimed the maximum tolerated dose (MTD) as 6/3mg on 08 July 2020 after 1 patient was already treated with 7/3.5mg, so the first patient in NC and all the following patients were treated with 6/3mg.
Patients in were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C).

Reporting group values	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 0.5 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999
Number of subjects	2	2	3
Age categorical			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			

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)	1	0	3
From 65-84 years	1	2	0
85 years and over	0	0	0

Age Continuous			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg . For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: years			
arithmetic mean	63.5	69.5	46.7
standard deviation	± 10.6	± 2.1	± 9.3

Sex: Female, Male			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Participants			
Female	1	0	2
Male	1	2	1

Race (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	2	2	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Ethnicity (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	2	3

Unknown or Not Reported	0	0	0

Reporting group values	Phase Ia - Schedule A: 1.5 mg BI 894999	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule A: 5 mg BI 894999
Number of subjects	6	6	2
Age categorical			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	3	1
From 65-84 years	1	3	1
85 years and over	0	0	0
Age Continuous			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg . For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: years			
arithmetic mean	57.5	53.5	54.5
standard deviation	± 11.9	± 18.1	± 26.2
Sex: Female, Male			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Participants			
Female	2	6	0
Male	4	0	2
Race (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0

Black or African American	0	0	0
White	6	6	2
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	6	5	2
Unknown or Not Reported	0	0	0

Reporting group values	Phase Ia - Schedule B: 1.5 mg BI 894999	Phase Ia - Schedule B: 2 mg BI 894999	Phase Ia - Schedule B: 2.5 mg BI 894999
Number of subjects	6	6	13
Age categorical			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	4	7
From 65-84 years	2	2	6
85 years and over	0	0	0
Age Continuous			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg . For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: years			
arithmetic mean	60.7	61.5	64.5
standard deviation	± 10.8	± 13.0	± 7.5
Sex: Female, Male			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Participants			
Female	3	1	4
Male	3	5	9

Race (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	6	6	13
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	6	6	13
Unknown or Not Reported	0	0	0

Reporting group values	Phase Ia - Schedule C: 5/2.5 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Number of subjects	4	15	12
Age categorical			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
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	2	5	4
85 years and over	0	0	0
Age Continuous			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg . For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: years			

arithmetic mean	63.3	59.7	62.5
standard deviation	± 12.8	± 12.0	± 6.5

Sex: Female, Male			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Participants			
Female	2	5	7
Male	2	10	5
Race (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	4	15	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
Hispanic or Latino	0	1	2
Not Hispanic or Latino	4	14	10
Unknown or Not Reported	0	0	0

Reporting group values	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)
Number of subjects	8	4	2
Age categorical			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
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	0	0
From 65-84 years	5	2	2
85 years and over	0	2	0
Age Continuous			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg . For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: years			
arithmetic mean	71.4	78.8	68.5
standard deviation	± 10.9	± 9.0	± 2.1
Sex: Female, Male			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Participants			
Female	1	1	1
Male	7	3	1
Race (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	2	4	2
More than one race	0	0	0
Unknown or Not Reported	6	0	0
Ethnicity (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	4	2
Unknown or Not Reported	6	0	0

Reporting group values	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (SCLC patients)

Number of subjects	2	2	12
Age categorical			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
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)	0	0	7
From 65-84 years	2	1	5
85 years and over	0	1	0
Age Continuous			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg . For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: years			
arithmetic mean	68.5	79.0	63.5
standard deviation	± 2.1	± 9.9	± 7.3
Sex: Female, Male			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Participants			
Female	0	1	5
Male	2	1	7
Race (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	1	0	7
More than one race	0	0	0
Unknown or Not Reported	1	2	4
Ethnicity (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to			

have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	1	8
Unknown or Not Reported	0	1	4

Reporting group values	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)
Number of subjects	14	11	20
Age categorical			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
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)	6	2	18
From 65-84 years	8	9	2
85 years and over	0	0	0
Age Continuous			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg . For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: years			
arithmetic mean	66.2	69.7	44.4
standard deviation	± 6.3	± 4.1	± 13.9
Sex: Female, Male			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Participants			
Female	6	0	5
Male	8	11	15
Race (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the			

MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	9	8	14
More than one race	0	0	0
Unknown or Not Reported	5	2	3
Ethnicity (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	8	9	17
Unknown or Not Reported	5	2	3

Reporting group values	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)	Total	
Number of subjects	22	174	
Age categorical			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	19	103	
From 65-84 years	3	68	
85 years and over	0	3	
Age Continuous			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg . For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: years			
arithmetic mean	40.5		
standard deviation	± 16.5	-	

Sex: Female, Male			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Participants			
Female	8	61	
Male	14	113	
Race (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	1	4	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	1	3	
White	16	140	
More than one race	0	0	
Unknown or Not Reported	4	27	
Ethnicity (NIH/OMB)			
Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment. For Phase Ib-Schedule B SCLC, Phase Ib-Schedule B mCRPC, DMC lowered the dose of SCLC and mCRPC, thus patients treated prior the decision took 2.5mg BI 894999 and patients treated after the decision received 2mg. For Phase Ib - Schedule C NC, the dose was lowered since DMC reclaimed the MTD as 6/3mg after 1 patient already treated with 7/3.5mg.			
Units: Subjects			
Hispanic or Latino	1	6	
Not Hispanic or Latino	17	143	
Unknown or Not Reported	4	25	

End points reporting groups

Reporting group title	Phase Ia - Schedule A: 0.2 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 0.2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 0.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 0.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 1 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 1.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 2 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 1.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in

cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2.5 mg of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule C: 5/2.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule C: 6/3 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule C: 7/3.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 7 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 4 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (SCLC patients)

Reporting group description:

This arm included adult patients diagnosed with small cell lung cancer (SCLC).
SCLC patients were initially administered 2.5 mg of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).
The Data Monitoring Committee decided on 28 November 2018 to lower the 2.5 mg BI 894999 dose due to safety concerns to 2mg, therefore patients treated before the decision were administered 2.5mg, and patients treated after the decision were administered 2mg.

Reporting group title	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)

Reporting group description:

Adult patients diagnosed with colorectal cancer (CRC) were administered orally 2.5 milligram (mg) of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).

Reporting group title	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)

Reporting group description:

This arm included adult patients diagnosed with metastatic castrate resistant prostate cancer (mCRPC).
MCRPC patients were initialy administered 2.5 mg of BI 894999. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).
The Data Monitoring Committee decided on 28 November 2018 to lower the 2.5 mg BI 894999 dose due to safety concerns to 2mg, therefore patients treated before the decision were administered 2.5mg, and patients treated after the decision were administered 2mg.

Reporting group title	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)

Reporting group description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days. The 2.5 mg dose could be reduced to 2 mg in case of adverse events.

Reporting group title	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)

Reporting group description:

This arm included adult patients diagnosed with NUT carcinoma (NC).
The DMC reclaimed the maximum tolerated dose (MTD) as 6/3mg on 08 July 2020 after 1 patient was already treated with 7/3.5mg, so the first patient in NC and all the following patients were treated with 6/3mg.
Patients in were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C).

Subject analysis set title	Phase Ib - Schedule C: BI 894999 7/3.5 mg (NC patients)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 7 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.
This Subject Analysis Set is reporting descriptive statistics for the endpoints AUC0-24 and Cmax.

Subject analysis set title	Phase Ib - Schedule B: BI 894999 2 mg (solid tumours+NC)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with one of the following cancer types small cell lung cancer (SCLC); metastatic castrate resistant prostate cancer (mCRPC); NUT carcinoma (NC) were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.
This Subject Analysis Set is reporting descriptive statistics for the endpoints AUC0-24 and Cmax.

Subject analysis set title	Phase Ib - Schedule B: BI 894999 2.5 mg (solid tumours + NC)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with one of the following cancer types small cell lung cancer (SCLC); metastatic castrate resistant prostate cancer (mCRPC); colorectal cancer (CRC); NUT carcinoma (NC) were administered orally 2.5 milligram (mg) of BI 894999, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.
This Subject Analysis Set is reporting descriptive statistics for the endpoint AUC0-24.

Subject analysis set title	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C).
This Subject Analysis Set is reporting descriptive statistics for the endpoint AUC0-24.

Subject analysis set title	Phase Ib - Schedule B: BI 894999 2.5 mg (solid tumours + NC)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with one of the following cancer types small cell lung cancer (SCLC); metastatic castrate resistant prostate cancer (mCRPC); colorectal cancer (CRC); NUT carcinoma (NC) were administered orally 2.5 milligram (mg) of BI 894999, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.
This Subject Analysis Set is reporting descriptive statistics for the endpoint Cmax.

Subject analysis set title	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C).
This Subject Analysis Set is reporting descriptive statistics for the endpoint Cmax.

Subject analysis set title	Phase Ib - Schedule C: BI 894999 7/3.5 mg (NC patients)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 7 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.
This subject analysis set is reporting descriptive statistics for the endpoints AUC_T, ss and Cmax, ss.

Subject analysis set title	Phase Ib - Schedule B: 2 mg BI 894999 (NC patients only)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with NUT carcinoma (NC) were administered during the first cycle 2.5 milligram (mg) BI 894999 according to Schedule B and then the dosage was decreased at steady state to 2 mg of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.
This subject analysis set is reporting descriptive statistics for the endpoints AUC_T, ss and Cmax, ss.

Subject analysis set title	Phase Ib - Schedule B: BI 894999 2 mg (solid tumours + NC)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with one of the following cancer types small cell lung cancer (SCLC); metastatic castrate resistant prostate cancer (mCRPC); NUT carcinoma (NC) were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.
This subject analysis set is reporting descriptive statistics for the endpoints AUC_T, ss and Cmax, ss.

Subject analysis set title	Phase Ib - Schedule B: BI 894999 2.5 mg (solid tumours + NC)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with one of the following cancer types small cell lung cancer (SCLC); metastatic castrate resistant prostate cancer (mCRPC); colorectal cancer (CRC); NUT carcinoma (NC) were administered orally 2.5 milligram (mg) of BI 894999, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.
This subject analysis set is reporting descriptive statistics for the endpoints AUC_T, ss and Cmax, ss.

Subject analysis set title	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)
Subject analysis set type	Per protocol

Subject analysis set description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C).
This subject analysis set is reporting descriptive statistics for the endpoints AUC_T, ss and Cmax, ss.

Primary: Phase Ia: Number of patients with Dose Limiting Toxicities (DLTs) observed in the first cycle

End point title	Phase Ia: Number of patients with Dose Limiting Toxicities (DLTs) observed in the first cycle[1][2]

End point description:

The following drug related adverse events (AEs) qualified as DLT:
- any Common Terminology Criteria for AEs (CTCAE) grade ≥3 non haematological toxicity considered related to trial medication with the following exceptions:
-- inadequately treated nausea, vomiting or diarrhoea. For fatigue, if present at baseline, there had to be an increase of ≥2 grades
-- electrolytes abnormalities that were corrected within 72 hours with treatment
- any haematologic AE related to the trial medication defined as follows:
-- CTCAE grade ≥4 neutropenia lasting ≥ 7 days and/or complicated by infection, or
-- CTCAE grade ≥4 thrombocytopenia, or
--CTCAE grade≥ 3 thrombocytopenia coupled with grade ≥ 2 of bleeding, or
-- febrile neutropenia CTCAE grade 3 or higher.
- any other drug-related AE preventing the patient from taking his treatment according to given schedule.
Maximum Tolerated Dose (MTD) Evaluation Set: Included all patients in the TS of Phase 1a who were not replaced for the MTD determination.

End point type	Primary

End point timeframe:

First treatment cycle (the first 21 days for Schedules A and B, the first 28 days for Schedule C).

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: Endpoint was analyzed only descriptively.

[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: Endpoint was specified only for the participants of the Phase1a.

End point values	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 0.5 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999	Phase Ia - Schedule A: 1.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[3]	2[4]	3[5]	6[6]
Units: Participants	0	0	0	0

Notes:

[3] - Maximum Tolerated Dose (MTD) Evaluation Set (MTDS)

[4] - MTDS

[5] - MTDS

[6] - MTDS

End point values	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule A: 5 mg BI 894999	Phase Ia - Schedule B: 1.5 mg BI 894999	Phase Ia - Schedule B: 2 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[7]	2[8]	5[9]	6[10]
Units: Participants	3	2	1	0

Notes:

[7] - MTDS

[8] - MTDS

[9] - MTDS

[10] - MTDS

End point values	Phase Ia - Schedule B: 2.5 mg BI 894999	Phase Ia - Schedule C: 5/2.5 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12[11]	3[12]	12[13]	10[14]
Units: Participants	2	0	2	4

Notes:

[11] - MTDS

[12] - MTDS

[13] - MTDS

[14] - MTDS

End point values	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8[15]	3[16]	2[17]	2[18]
Units: Participants	1	1	2	0

Notes:

[15] - MTDS

[16] - MTDS

[17] - MTDS

[18] - MTDS

End point values	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL			

	patients)			
Subject group type	Reporting group			
Number of subjects analysed	2[19]			
Units: Participants	0			

Notes:

[19] - MTDS

Statistical analyses

No statistical analyses for this end point

Primary: Phase Ib: Number of patients with Dose Limiting Toxicities (DLTs) observed during the on-treatment period

End point title	Phase Ib: Number of patients with Dose Limiting Toxicities (DLTs) observed during the on-treatment period[20][21]

End point description:

The following drug related adverse events (AEs) qualified as DLT:
- any Common Terminology Criteria for Adverse Events (CTCAE) grade ≥3 non haematological toxicity considered related to trial medication with the following exceptions:
-- inadequately treated nausea, vomiting or diarrhoea. For fatigue, if present at baseline, there had to be an increase of ≥2 grades
-- electrolytes abnormalities that were corrected within 72 hours with treatment
- any haematologic AE related to the trial medication defined as follows:
-- CTCAE grade ≥4 neutropenia lasting ≥ 7 days and/or complicated by infection, or
-- CTCAE grade ≥4 thrombocytopenia, or
--CTCAE grade≥ 3 thrombocytopenia coupled with grade ≥ 2 of bleeding, or
-- febrile neutropenia CTCAE grade 3 or higher.
- any other drug-related AE preventing the patient from taking his treatment according to the given schedule.
Treated Set in Phase Ib dose expansion (TS PhIb): All patients in the TS who were treated in Phase Ib.

End point type	Primary

End point timeframe:

Date of the first administration of study treatment until date of the last administration of study treatment + 30 days residual effect period, up to 883 days.

Notes:

[20] - 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: Endpoint was analyzed only descriptively.

[21] - 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: Endpoint was specified only for the participants of the Phase 1b.

End point values	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (SCLC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12[22]	14[23]	11[24]	20[25]
Units: Participants	3	2	7	2

Notes:

[22] - Treated Set (TS) in Phase Ib dose expansion (TS PhIb).

[23] - TS PhIb

[24] - TS PhIb

[25] - TS PhIb

End point values	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)			
Subject group type	Reporting group			
Number of subjects analysed	22[26]			
Units: Participants	3			

Notes:

[26] - TS PhIb

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ia: Number of patients with Dose Limiting Toxicities (DLTs) observed during the on-treatment period

End point title	Phase Ia: Number of patients with Dose Limiting Toxicities (DLTs) observed during the on-treatment period[27]

End point description:

The following drug related adverse events (AEs) qualified as DLT:
- any Common Terminology Criteria for AEs (CTCAE) grade ≥3 non haematological toxicity considered related to trial medication with the following exceptions:
-- inadequately treated nausea, vomiting or diarrhoea. For fatigue, if present at baseline, there had to be an increase of ≥2 grades
-- electrolytes abnormalities that were corrected within 72 hours with treatment
- any haematologic AE related to the trial medication defined as follows:
-- CTCAE grade ≥4 neutropenia lasting ≥ 7 days and/or complicated by infection, or
-- CTCAE grade ≥4 thrombocytopenia, or
--CTCAE grade≥ 3 thrombocytopenia coupled with grade ≥ 2 of bleeding, or
-- febrile neutropenia CTCAE grade 3 or higher.
- any other drug-related AE preventing the patient from taking his treatment according to the given schedule.

End point type	Secondary

End point timeframe:

Date of the first administration of study treatment until date of the last administration of study treatment + 30 days residual effect period, up to 463 days.

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: Endpoint was specified only for the participants of the Phase 1a.

End point values	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 0.5 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999	Phase Ia - Schedule A: 1.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[28]	2[29]	3[30]	6[31]
Units: Participants	0	0	0	2

Notes:

[28] - Treated Set in Phase 1a

[29] - Treated Set in Phase 1a

[30] - Treated Set in Phase 1a

[31] - Treated Set in Phase 1a

End point values	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule A: 5 mg BI 894999	Phase Ia - Schedule B: 1.5 mg BI	Phase Ia - Schedule B: 2 mg BI 894999

			894999	
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[32]	2[33]	6[34]	6[35]
Units: Participants	4	2	1	0

Notes:

[32] - Treated Set in Phase 1a

[33] - Treated Set in Phase 1a

[34] - Treated Set in Phase 1a

[35] - Treated Set in Phase 1a

End point values	Phase Ia - Schedule B: 2.5 mg BI 894999	Phase Ia - Schedule C: 5/2.5 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13[36]	4[37]	15[38]	12[39]
Units: Participants	3	1	3	4

Notes:

[36] - Treated Set in Phase 1a

[37] - Treated Set in Phase 1a

[38] - Treated Set in Phase 1a

[39] - Treated Set in Phase 1a

End point values	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8[40]	4[41]	2[42]	2[43]
Units: Participants	1	2	2	1

Notes:

[40] - Treated Set in Phase 1a

[41] - Treated Set in Phase 1a

[42] - Treated Set in Phase 1a

[43] - Treated Set in Phase 1a

End point values	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)			
Subject group type	Reporting group			
Number of subjects analysed	2[44]			
Units: Participants	2			

Notes:

[44] - Treated Set in Phase 1a

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ia and Phase Ib: Area under the concentration-time curve of BI 894999 in plasma over the time interval from 0 to 24 hours after administration of the first dose (AUC0-24)

End point title	Phase Ia and Phase Ib: Area under the concentration-time curve of BI 894999 in plasma over the time interval from 0 to 24 hours after administration of the first dose (AUC0-24)[45]

End point description:

Area under the concentration-time curve of BI 894999 in plasma over the time interval from 0 to 24 hours after administration of the first dose (AUC0-24) for Phase Ia and Phase Ib is reported.
999999=NA- Could not be calculated due to low number of participants with valid AUC0-24 values.

Pharmacokinetic (PK) analysis Set (PKS): Included all patients in the treated set (TS) who have at least one evaluable PK parameters. Only participants with evaluable results for this PK parameter are reported.

End point type	Secondary

End point timeframe:

5 minutes (min) before and at 30 min, 1 hour (h), 2h, 3h, 4h, 6h, 8h and 23h55min after administration of first BI 894999 dose on Day 1 of Cycle 1.

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: In phase Ib, solid tumor patients (SCLC, mCRPC, CRC and NC) are combined by dose level (2 or 2.5mg) as data of all solid tumor patients were needed since no differences were expected, but the NC patients alone were differentiated in an additional subgroup as it was the initial indication for BI 894999.

End point values	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 0.5 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999	Phase Ia - Schedule A: 1.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	5
Units: nanomole * hour /Liter (nmol*h/L)				
geometric mean (geometric coefficient of variation)	4.36 (± 21.1)	6.43 (± 2.78)	20.5 (± 16.8)	34.0 (± 69.4)

End point values	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule A: 5 mg BI 894999	Phase Ia - Schedule B: 1.5 mg BI 894999	Phase Ia - Schedule B: 2 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	0[46]	3	4
Units: nanomole * hour /Liter (nmol*h/L)				
geometric mean (geometric coefficient of variation)	64.9 (± 71.0)	()	27.7 (± 81.5)	44.8 (± 34.8)

Notes:

[46] - No subjects in this arm were analyzed for this endpoint.

End point values	Phase Ia - Schedule B: 2.5 mg BI 894999	Phase Ia - Schedule C: 5/2.5 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	4	15	12
Units: nanomole * hour /Liter (nmol*h/L)				
geometric mean (geometric coefficient	51.5 (± 41.7)	123 (± 37.6)	212 (± 45.5)	230 (± 27.3)

of variation)

End point values	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	4	2	2
Units: nanomole * hour /Liter (nmol*h/L)				
geometric mean (geometric coefficient of variation)	31.7 (± 33.4)	48.0 (± 26.9)	53.3 (± 6.91)	138 (± 7.52)

End point values	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)	Phase Ib - Schedule C: BI 894999 7/3.5 mg (NC patients)	Phase Ib - Schedule B: BI 894999 2 mg (solid tumours+NC)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	0[47]	17	1	9
Units: nanomole * hour /Liter (nmol*h/L)				
geometric mean (geometric coefficient of variation)	()	56.9 (± 58.6)	999999 (± 999999)	39.2 (± 38.8)

Notes:

[47] - No subjects in this arm were analyzed for this endpoint.

End point values	Phase Ib - Schedule B: BI 894999 2.5 mg (solid tumours + NC)	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	2		
Units: nanomole * hour /Liter (nmol*h/L)				
geometric mean (geometric coefficient of variation)	67.6 (± 50.9)	214 (± 6.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ia and Phase Ib: Maximum measured concentration of BI 894999 in plasma after the first dose (Cmax)

End point title	Phase Ia and Phase Ib: Maximum measured concentration of BI 894999 in plasma after the first dose (Cmax)[48]

End point description:

Maximum measured concentration of BI 894999 in plasma after the first dose (Cmax) for Phase 1a and Phase 1b is reported.
999999=NA- Cmax could not be provided to reduce the risk of patient re-identificaton.

Pharmacokinetic (PK) analysis Set (PKS): Included all patients in the treated set (TS) who have at least one evaluable PK parameters. Only participants with evaluable results for this PK parameter are reported.

End point type	Secondary

End point timeframe:

5 minutes (min) before and at 30 min, 1 hour (h), 2h, 3h, 4h, 6h, 8h and 23h55min after administration of first BI 894999 dose on Day 1 of Cycle 1.

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: In phase Ib, solid tumor patients (SCLC, mCRPC, CRC and NC) are combined by dose level (2 or 2.5mg) as data of all solid tumor patients were needed since no differences were expected, but the NC patients alone were differentiated in an additional subgroup as it was the initial indication for BI 894999.

End point values	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 0.5 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999	Phase Ia - Schedule A: 1.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	5
Units: nanomole/L (nmol/L)				
geometric mean (geometric coefficient of variation)	0.393 (± 35.6)	0.569 (± 46.2)	1.75 (± 31.6)	3.79 (± 84.0)

End point values	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule A: 5 mg BI 894999	Phase Ia - Schedule B: 1.5 mg BI 894999	Phase Ia - Schedule B: 2 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	3	4
Units: nanomole/L (nmol/L)				
geometric mean (geometric coefficient of variation)	7.39 (± 56.0)	16.2 (± 68.0)	3.00 (± 155)	3.93 (± 50.2)

End point values	Phase Ia - Schedule B: 2.5 mg BI 894999	Phase Ia - Schedule C: 5/2.5 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	4	15	12
Units: nanomole/L (nmol/L)				
geometric mean (geometric coefficient of variation)	4.48 (± 46.6)	12.0 (± 85.1)	19.4 (± 58.4)	21.0 (± 48.3)

End point values	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	4	2	2
Units: nanomole/L (nmol/L)				
geometric mean (geometric coefficient of variation)	2.98 (± 34.9)	4.49 (± 36.0)	4.75 (± 0.595)	13.9 (± 12.8)

End point values	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)	Phase Ib - Schedule C: BI 894999 7/3.5 mg (NC patients)	Phase Ib - Schedule B: BI 894999 2 mg (solid tumours+NC)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	1	17	1	9
Units: nanomole/L (nmol/L)				
geometric mean (geometric coefficient of variation)	999999 (± 999999)	4.88 (± 50.1)	999999 (± 999999)	4.10 (± 37.8)

End point values	Phase Ib - Schedule B: BI 894999 2.5 mg (solid tumours + NC)	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	44	15		
Units: nanomole/L (nmol/L)				
geometric mean (geometric coefficient of variation)	6.01 (± 59.6)	18.8 (± 55.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ia and Phase Ib: Area under the concentration-time curve of BI 894999 in plasma at steady state over a uniform dosing interval τ (AUCτ, ss)

End point title	Phase Ia and Phase Ib: Area under the concentration-time curve of BI 894999 in plasma at steady state over a uniform dosing interval τ (AUCτ, ss)[49]

End point description:

Area under the concentration-time curve of BI 894999 in plasma at steady state over a uniform dosing interval τ (AUCτ, ss) for Phase Ia and Ib is reported. The dosing interval is 24 hours (h) for all dose groups.
999999=NA-AUCτ, ss could not be provided to reduce the risk of patient re-identification.
Pharmacokinetic (PK) analysis Set (PKS): Included all patients in the treated set (TS) who have at least one evaluable PK parameters. Only participants with evaluable results for this PK parameter are reported.

End point type	Secondary

End point timeframe:

5 minutes (min) before and at 30 min, 1 hour (h), 2h, 3h, 4h, 6h, 8h, and at 23h55min (Schedule A) or 24h (Schedule B & C) following administration on day 14 (Schedule A & B) or day 21 (Schedule C).

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: In phase Ib, solid tumor patients (SCLC, mCRPC, CRC and NC) are combined by dose level (2 or 2.5mg) as data of all solid tumor patients were needed since no differences were expected, but the NC patients alone were differentiated in an additional subgroup as it was the initial indication for BI 894999.

End point values	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 0.5 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999	Phase Ia - Schedule A: 1.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	4
Units: nanomole *hour/Liter (nmol*h/)L				
geometric mean (geometric coefficient of variation)	10.3 (± 72.6)	17.9 (± 46.4)	54.6 (± 40.4)	76.4 (± 26.6)

End point values	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule A: 5 mg BI 894999	Phase Ia - Schedule B: 1.5 mg BI 894999	Phase Ia - Schedule B: 2 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	4	6
Units: nanomole *hour/Liter (nmol*h/)L				
geometric mean (geometric coefficient of variation)	119 (± 90.3)	999999 (± 999999)	62.6 (± 49.2)	81.1 (± 32.1)

End point values	Phase Ia - Schedule B: 2.5 mg BI 894999	Phase Ia - Schedule C: 5/2.5 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	3	14	5
Units: nanomole *hour/Liter (nmol*h/)L				
geometric mean (geometric coefficient of variation)	87.0 (± 28.3)	144 (± 46.4)	176 (± 37.0)	226 (± 63.2)

End point values	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	1	1
Units: nanomole *hour/Liter (nmol*h/)L				
geometric mean (geometric coefficient	70.3 (± 38.5)	120 (± 19.6)	999999 (±	999999 (±

of variation)		999999)	999999)

End point values	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)	Phase Ib - Schedule C: BI 894999 7/3.5 mg (NC patients)	Phase Ib - Schedule B: 2 mg BI 894999 (NC patients only)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	1	14	0[50]	1
Units: nanomole *hour/Liter (nmol*h/)L				
geometric mean (geometric coefficient of variation)	999999 (± 999999)	94.9 (± 43.9)	()	999999 (± 999999)

Notes:

[50] - No subjects in this arm were analyzed for this endpoint.

End point values	Phase Ib - Schedule B: BI 894999 2 mg (solid tumours + NC)	Phase Ib - Schedule B: BI 894999 2.5 mg (solid tumours + NC)	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	33	11	
Units: nanomole *hour/Liter (nmol*h/)L				
geometric mean (geometric coefficient of variation)	73.6 (± 58.2)	125 (± 50.4)	149 (± 56.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ia and Phase Ib: Maximum measured concentration of BI 894999 in plasma at steady state over a uniform dosing interval τ (Cmax, ss)

End point title	Phase Ia and Phase Ib: Maximum measured concentration of BI 894999 in plasma at steady state over a uniform dosing interval τ (Cmax, ss)[51]

End point description:

Maximum measured concentration of BI 894999 in plasma at steady state over a uniform dosing interval τ (Cmax, ss) for Phase Ia and Phase Ib is reported. The dosing interval is 24 hours (h) for all dose groups.
999999=NA-Cmax, ss could not be provided to reduce the risk of patient re-identification.

Pharmacokinetic (PK) analysis Set (PKS): Included all patients in the treated set (TS) who have at least one evaluable PK parameters. Only participants with evaluable results for this PK parameter are reported.

End point type	Secondary

End point timeframe:

5 minutes (min) before and at 30 min, 1 hour (h), 2h, 3h, 4h, 6h, 8h, and at 23h55min (Schedule A) or 24h (Schedule B & C) following administration on day 14 (Schedule A & B) or day 21 (Schedule C).

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: In phase Ib, solid tumor patients (SCLC, mCRPC, CRC and NC) are combined by dose level

(2 or 2.5mg) as data of all solid tumor patients were needed since no differences were expected, but the NC patients alone were differentiated in an additional subgroup as it was the initial indication for BI 894999.

End point values	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 0.5 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999	Phase Ia - Schedule A: 1.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	6
Units: nanomole/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	0.697 (± 59.8)	1.26 (± 24.9)	4.06 (± 61.7)	5.25 (± 60.1)

End point values	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule A: 5 mg BI 894999	Phase Ia - Schedule B: 1.5 mg BI 894999	Phase Ia - Schedule B: 2 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	1	4	6
Units: nanomole/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	11.6 (± 54.4)	999999 (± 999999)	4.75 (± 46.9)	5.62 (± 27.7)

End point values	Phase Ia - Schedule B: 2.5 mg BI 894999	Phase Ia - Schedule C: 5/2.5 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	3	14	5
Units: nanomole/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	6.94 (± 42.0)	11.4 (± 56.1)	13.1 (± 41.8)	17.1 (± 63.6)

End point values	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	1	1
Units: nanomole/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	5.48 (± 32.7)	7.67 (± 8.44)	999999 (± 999999)	999999 (± 999999)

End point values	Phase Ia - Schedule C: BI	Phase Ib - Schedule B:	Phase Ib - Schedule C: BI	Phase Ib - Schedule B: 2

	894999 5/2.5 mg (DLBCL patients)	2.5 mg BI 894999 (NC patients)	894999 7/3.5 mg (NC patients)	mg BI 894999 (NC patients only)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	1	14	0[52]	1
Units: nanomole/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	999999 (± 999999)	7.68 (± 45.4)	()	999999 (± 999999)

Notes:

[52] - No subjects were analyzed in this arm for this endpoint.

End point values	Phase Ib - Schedule B: BI 894999 2 mg (solid tumours + NC)	Phase Ib - Schedule B: BI 894999 2.5 mg (solid tumours + NC)	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	10	33	11	
Units: nanomole/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	6.51 (± 70.0)	10.4 (± 59.4)	11.2 (± 60.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ia and Phase Ib: Objective response (OR)

End point title	Phase Ia and Phase Ib: Objective response (OR)

End point description:

OR was defined as best overall response (BOR) of complete response (CR) or partial response (PR) with tumour assessment during treatment period for each schedule.
For DLBCL patients, a minor response according to Response Evaluation Criteria In Lymphoma 2017 (RECIL 2017) was not part of an objective response.
BOR was determined from first treatment administration until the earliest of disease progression, death or last evaluable tumour assessment before start of subsequent anticancer therapy, loss to follow-up or withdrawal of consent, according to the following criteria depending on the type of cancer:
- solid tumour patients and mCRPC patients with measurable disease: CT and/ or MRI according to RECIST v1.1, every 2 cycles;
- mCRPC patients without measurable disease: bone scan and PSA level according to Prostate Cancer Clinical Trials Working Group 3, every 4 cycles;
- DLBCL patients:FDG-PET/CT scans according to RECIL 2017; every 2 cycles.

End point type	Secondary

End point timeframe:

Up to 15 months for Phase 1a and up to 28 months for Phase Ib.

End point values	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 0.5 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999	Phase Ia - Schedule A: 1.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	6
Units: Participants	0	1	0	1

End point values	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule A: 5 mg BI 894999	Phase Ia - Schedule B: 1.5 mg BI 894999	Phase Ia - Schedule B: 2 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	2	6	6
Units: Participants	0	0	1	0

End point values	Phase Ia - Schedule B: 2.5 mg BI 894999	Phase Ia - Schedule C: 5/2.5 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	4	15	12
Units: Participants	0	0	0	0

End point values	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	4	2	2
Units: Participants	0	1	0	0

End point values	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (SCLC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	12	14	11
Units: Participants	0	0	0	1

End point values	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	22		
Units: Participants	1	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: Progression-free survival or (PFS) or radiological PFS for mCRPC patients with non-measurable disease by RECIST v1.1

End point title	Phase Ib: Progression-free survival or (PFS) or radiological PFS for mCRPC patients with non-measurable disease by RECIST v1.1[53]

End point description:

Progression-free survival (PFS) was defined as the time from date of start of BI 894999 to the date of objective disease progression ((PD) defined as 20% increase in the sum of the longest diameter of target lesions) or death, whichever is earlier for SCLC patients, CRC patients, mCRPC patients with measurable disease by Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.1) and NC patients, with tumour assessment every 2 cycles according to RECIST v1.1 during treatment period or Radiological PFS with tumour assessment by bone scan every 4 cycles for mCRPC patients with non-measurable disease by RECIST v1.1.

For patients with 'event' as an outcome for PFS:
- PFS [days] = date of outcome – date of first treatment administration + 1.
For patients with 'censored' as an outcome for PFS:
- PFS (censored) [days] = date of outcome – date of first treatment administration + 1.
The Kaplan-Meier method was used to calculate the estimates.

End point type	Secondary

End point timeframe:

Up to 28 months.

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: Endpoint was specified only for metastatic Castration Resistant Prostate Cancer (mCRPC) patients in Phase Ib.

End point values	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (SCLC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12[54]	14[55]	11[56]	20[57]
Units: Weeks				
median (confidence interval 95%)	5.6 (5.3 to 6.1)	5.6 (4.4 to 10.7)	11.9 (8.1 to 24.4)	6.9 (6.0 to 11.1)

Notes:

[54] - Treated Set (TS) in Phase Ib dose expansion (TS PhIb).

[55] - TS PhIb

[56] - TS PhIb

[57] - TS PhIb

End point values	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)			
Subject group type	Reporting group			
Number of subjects analysed	22[58]			
Units: Weeks				
median (confidence interval 95%)	7.8 (4.0 to 13.0)			

Notes:

[58] - TS PhIb

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: Best overall response

End point title	Phase Ib: Best overall response[59]

End point description:

Best overall response (BOR) was determined from first treatment administration until the earliest of disease progression, death or last evaluable tumour assessment before start of subsequent anticancer therapy, loss to follow-up or withdrawal of consent, according to the following criteria depending on the type of cancer:
- solid tumour patients and mCRPC patients with measurable disease: Computerized tomography (CT) and/ or magnetic resonance imaging (MRI) according to RECIST v1.1, every 2 cycles;
- mCRPC patients without measurable disease: bone scan and PSA level according to Prostate Cancer Clinical Trials Working Group 3, every 4 cycles.
Treated Set (TS) in Phase Ib dose expansion (TS PhIb): Included all patients in the TS who were treated in Phase Ib.

End point type	Secondary

End point timeframe:

Imaging and assessment performed every 2 cycles (solid tumours patients) or 4 cycles (mCRPC patients) for the entire treatment period, up to 28 months.

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: Endpoint was specified only for the participants of the Phase 1b.

End point values	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (SCLC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	11	20
Units: Participants				
Complete response	0	0	0	0
Partial response	0	0	1	1
Stable disease	1	2	2	7
Progressive disease	8	10	4	9
Not evaluable	3	2	4	3

Not assessed	0	0	0	0

End point values	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: Participants				
Complete response	1			
Partial response	1			
Stable disease	6			
Progressive disease	9			
Not evaluable	5			
Not assessed	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: Prostate Specific Antigen (PSA) response in patients with Metastatic Castration Resistant Prostate Cancer (mCRPC)

End point title	Phase Ib: Prostate Specific Antigen (PSA) response in patients with Metastatic Castration Resistant Prostate Cancer (mCRPC)[60]

End point description:

PSA response was defined as a decline in PSA value ≥50% from baseline (which is confirmed by a second value 3 to 4 weeks apart).

mCRPC Schedule B in Phase Ib dose expansion (mCRPC): Included all mCRPC patients in the treated set who were treated in Phase Ib with Schedule B.

End point type	Secondary

End point timeframe:

Up to 93 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: Endpoint was specified only for metastatic Castration Resistant Prostate Cancer (mCRPC) patients in Phase Ib.

End point values	Phase Ib - Schedule B: 2 or 2.5 mg BI 894999 (mCRPC patients)			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib: Overall survival

End point title	Phase Ib: Overall survival[61]

End point description:

Overall survival (OS) was defined as the time from first administration of BI 894999 until death from any cause in patients with NUT carcinoma.
For patients with 'event' as an outcome for OS:
- OS [days] = date of outcome – date of first treatment administration + 1.
For patients with 'censored' as an outcome for OS:
- OS (censored) [days] = date of outcome – date of first treatment administration + 1.
The Kaplan-Meier method was used to calculate the estimates.
+(-)999999=NA-Could not be calculated due to low number of participants with missing values.
Patients in NC Schedules B and C in Phase Ib dose expansion and after approval of protocol version 11.0 and gave consent to the collection of overall survival status.

End point type	Secondary

End point timeframe:

Up to 28 months.

Notes:

[61] - 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: Endpoint was specified only for NUT carcinoma patients in Phase Ib.

End point values	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)	Phase Ib - Schedule C: 6/3 or 7/3.5 mg BI 894999 (NC patients)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	22		
Units: Weeks				
median (confidence interval 95%)	6.6 (-999999 to 999999)	15.4 (7.6 to 32.3)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

[Serious and Other Adverse Events]: From first date of dosing of study treatment until date of the last dosing of study treatment + 30 days residual effect period, up to 463 days for Phase 1a and up to 883 days for Phase Ib.

Adverse event reporting additional description:

[All-Cause Mortality]: From first date of dosing until end of study, up to 1309 days for Phase Ia and up to 860 days for Phase Ib.

Treated Set (TS): Included all patients who were dispensed study treatment and were documented to have taken at least one dose of the study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Phase Ia - Schedule A: 0.2 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 0.2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 1 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 1.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 2 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule C: 6/3 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule B: 1.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid

tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 2.5 mg of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule C: 5/2.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule A: 0.5 mg BI 89499

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 0.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule A: 5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally 5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule A was a continuous daily intake in cycles of 21 days.

Reporting group title	Phase Ia - Schedule C: 7/3.5 mg BI 894999

Reporting group description:

Adult patients with a confirmed diagnosis of advanced, unresectable and/or metastatic malignant solid tumours who had failed conventional treatment or for whom no therapy of proven efficacy existed or who were not amenable to standard therapies were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 7 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 3.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 1.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ib - Schedule B: 2.5 mg BI 894999 (SCLC patients)

Reporting group description:

Adult patients diagnosed with small cell lung cancer (SCLC) were administered 2.5 milligram (mg) of BI 894999 once daily. BI 894999 administration was performed in the morning, after an overnight fast, 1

hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).

Reporting group title	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 5 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2.5 mg of BI 894999, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 4 milligram (mg) of BI 894999, followed by six days daily intake of the maintenance dose of 2 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning,
after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Reporting group title	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)

Reporting group description:

Adult patients with histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ib - Schedule B: 2 mg BI 894999 (SCLC patients)

Reporting group description:

Adult patients diagnosed with small cell lung cancer (SCLC) were administered orally 2 milligram (mg) of BI 894999 once daily. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).

Reporting group title	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)

Reporting group description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 6 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C).

Reporting group title	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)

Reporting group description:

Adult patients diagnosed with NUT carcinoma (NC) were administered orally 2.5 milligram (mg) of BI 894999 once daily, in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water. Schedule B was a continuous intake for 14 days followed by one week off treatment in cycles of 21 days. The 2.5 mg dose could be reduced to 2 mg in case of adverse events.

Reporting group title	Phase Ib - Schedule B: 2 mg BI 894999 (mCRPC patients)

Reporting group description:

Adult patients diagnosed with metastatic castrate resistant prostate cancer (mCRPC) were administered orally 2 milligram (mg) of BI 894999 once daily. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days.

Reporting group title	Phase Ib - Schedule B: 2.5 mg BI 894999 (mCRPC patients)

Reporting group description:

Adult patients diagnosed with metastatic castrate resistant prostate cancer (mCRPC) were administered orally 2.5 milligram (mg) of BI 894999 once daily. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of

21 days).

Reporting group title	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)

Reporting group description:

Adult patients diagnosed with colorectal cancer (CRC) were administered orally 2.5 milligram (mg) of BI 894999 once daily. BI 894999 administration was performed in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water according to Schedule B (continuous intake for 14 days followed by one week off treatment in cycles of 21 days).

Reporting group title	Phase Ib - Schedule C: BI 894999 7/3.5 mg (NC patients)

Reporting group description:

This arm included adult patients diagnosed with NUT carcinoma (NC) who were administered orally once daily on Day 1 and on Day 15 of each cycle a loading dose of 7 milligram (mg) of BI 894999, followed by six days intake of the maintenance dose of 3.5 mg of BI 894999 once daily, followed by one week off, repeated every two weeks in cycles of 28 days (Schedule C). The loading and the maintenance dose were administered in the morning, after an overnight fast, 1 hour before breakfast with at least 250 milliliter (mL) of water.

Serious adverse events	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999	Phase Ia - Schedule A: 1.5 mg BI 894999
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	3 / 6 (50.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to spinal cord			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 occlusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Euthanasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Bronchial obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (50.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Increased bronchial secretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 fistula			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 MB increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 T increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiogenic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Cerebrovascular accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Eye haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 necrosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder dilatation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryocystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule B: 1.5 mg BI 894999
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	8 / 15 (53.33%)	3 / 6 (50.00%)
number of deaths (all causes)	1	2	1
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to spinal cord			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 occlusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Euthanasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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			
Bronchial obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Increased bronchial secretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 MB increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 ST segment elevation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 T wave inversion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 T increased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 15 (13.33%)	0 / 6 (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
Injury, poisoning and procedural			

complications			
Fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiogenic shock			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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			
Cerebrovascular accident			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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			
Eye haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 necrosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder dilatation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryocystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
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 / 15 (0.00%)	0 / 6 (0.00%)
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	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase Ia - Schedule B: 2 mg BI 894999	Phase Ia - Schedule B: 2.5 mg BI 894999	Phase Ia - Schedule C: 5/2.5 mg BI 894999
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	6 / 13 (46.15%)	2 / 4 (50.00%)
number of deaths (all causes)	1	2	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 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 spinal cord			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (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 associated fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 occlusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Euthanasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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%)	1 / 13 (7.69%)	0 / 4 (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
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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			
Bronchial obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (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
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (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
Increased bronchial secretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (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
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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 / 4 (0.00%)
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 / 4 (0.00%)
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 ST segment elevation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 T wave inversion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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 T increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (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
Injury, poisoning and procedural			

complications			
Fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiogenic shock			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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 / 4 (0.00%)
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			
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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			
Eye haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (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 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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			
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 necrosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder dilatation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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 retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryocystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)
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 / 4 (0.00%)
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 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase Ia - Schedule A: 0.5 mg BI 89499	Phase Ia - Schedule A: 5 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	1 / 2 (50.00%)	8 / 12 (66.67%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Malignant neoplasm progression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 spinal cord			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Tumour associated fever			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Tumour haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Jugular vein distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 occlusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Surgical and medical procedures			
Euthanasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (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
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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 / 1
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
General physical health deterioration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	1 / 2 (50.00%)	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
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Increased bronchial secretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Laryngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Laryngeal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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	0 / 2 (0.00%)	0 / 2 (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
Pneumonitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Pulmonary congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 fistula			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 MB increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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	0 / 2 (0.00%)	0 / 2 (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 creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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 T increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Injury, poisoning and procedural			

complications			
Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Subdural haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Tendon rupture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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

Cardiogenic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (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
Ischaemic stroke			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Eye haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Uveitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Duodenal ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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
Oral pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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			
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 necrosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Bladder dilatation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Calculus urinary			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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
Osteonecrosis of jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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 jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Dacryocystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Localised infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Meningitis pneumococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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	0 / 2 (0.00%)	0 / 2 (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 aspiration			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	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
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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 / 2 (0.00%)	0 / 2 (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
Hyponatraemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (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

Serious adverse events	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (SCLC patients)	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 8 (37.50%)	2 / 3 (66.67%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spinal cord			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein distension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular occlusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Euthanasia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Increased bronchial secretion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (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
Laryngeal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fistula			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (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
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
Fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiogenic shock			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 3 (66.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Eye haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin necrosis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder dilatation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain in extremity			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in jaw			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryocystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infection			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	2 / 2 (100.00%)	2 / 4 (50.00%)
number of deaths (all causes)	1	0	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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 spinal cord			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 associated fever			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 occlusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Euthanasia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (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
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Increased bronchial secretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 fistula			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 MB increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 ST segment elevation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 T wave inversion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 T increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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			
Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiogenic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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			
Cerebrovascular accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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			
Eye haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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			
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 necrosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder dilatation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryocystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (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
Spinal cord infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase Ib - Schedule B: 2 mg BI 894999 (SCLC patients)	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 9 (33.33%)	12 / 21 (57.14%)	15 / 20 (75.00%)
number of deaths (all causes)	1	2	5
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 / 9 (0.00%)	0 / 21 (0.00%)	3 / 20 (15.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 spinal cord			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 associated fever			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Jugular vein distension			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Vascular occlusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Surgical and medical procedures			
Euthanasia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Death			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Disease progression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	1 / 21 (4.76%)	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 physical health deterioration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Pyrexia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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			
Bronchial obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Dyspnoea			
subjects affected / exposed	1 / 9 (11.11%)	2 / 21 (9.52%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Increased bronchial secretion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Laryngeal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Laryngeal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	3 / 21 (14.29%)	0 / 20 (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
Pneumonitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Pneumothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Pulmonary congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Pulmonary fistula			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Pulmonary haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 MB increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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 ST segment elevation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 T wave inversion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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			
Fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Subdural haematoma			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Tendon rupture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Wound			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Cardiac arrest			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 congestive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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

Cardiogenic shock			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Pericardial effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Ischaemic stroke			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Neuralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Somnolence			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Spinal cord compression			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Eye haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Uveitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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
Duodenal ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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
Oral pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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			
Dermatitis acneiform			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Skin necrosis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	1 / 21 (4.76%)	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 / 1	0 / 0
Bladder dilatation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Calculus urinary			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 retention			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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
Osteonecrosis of jaw			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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 jaw			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
COVID-19			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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 / 1	0 / 0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Dacryocystitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Device related infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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
Localised infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Meningitis pneumococcal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	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
Pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 21 (4.76%)	5 / 20 (25.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Spinal cord infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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 / 9 (0.00%)	0 / 21 (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			
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	3 / 20 (15.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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	1 / 9 (11.11%)	0 / 21 (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
Hypophosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (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

Serious adverse events	Phase Ib - Schedule B: 2 mg BI 894999 (mCRPC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (mCRPC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	8 / 10 (80.00%)	8 / 14 (57.14%)
number of deaths (all causes)	0	0	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 / 1 (0.00%)	0 / 10 (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
Malignant neoplasm progression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 spinal cord			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 associated fever			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	1 / 10 (10.00%)	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
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Jugular vein distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 occlusion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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
Surgical and medical procedures			
Euthanasia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Death			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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	0 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	0 / 10 (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 health deterioration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Increased bronchial secretion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Laryngeal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Laryngeal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Pneumonitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 fistula			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 creatine phosphokinase MB increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	0 / 10 (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 ST segment elevation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 T wave inversion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Platelet count decreased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (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
Troponin I increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Troponin T increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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			
Fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Subdural haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Tendon rupture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Wound			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 arrest			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 congestive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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

Cardiogenic shock			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Pericardial effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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	0 / 1 (0.00%)	0 / 10 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Ischaemic stroke			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Somnolence			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Spinal cord compression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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			
Eye haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Uveitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	0 / 10 (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
Duodenal ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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 / 1 (0.00%)	1 / 10 (10.00%)	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
Oral pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Small intestinal haemorrhage			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	3 / 14 (21.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Cholangitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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			
Dermatitis acneiform			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 necrosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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	0 / 1 (0.00%)	1 / 10 (10.00%)	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
Bladder dilatation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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
Calculus urinary			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Osteonecrosis of jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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

Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Pain in jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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			
Abdominal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Dacryocystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Device related infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Localised infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Meningitis pneumococcal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	0 / 10 (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 aspiration			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	0 / 10 (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
Spinal cord infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (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 / 1 (0.00%)	1 / 10 (10.00%)	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
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	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

Serious adverse events	Phase Ib - Schedule C: BI 894999 7/3.5 mg (NC patients)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm progression			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to spinal cord			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour associated fever			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour haemorrhage			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolism			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Jugular vein distension			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular occlusion			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Euthanasia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration			

site conditions				
Asthenia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chest pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Death				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disease progression				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	1 / 1 (100.00%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				

subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Increased bronchial secretion			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal inflammation			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal obstruction			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonitis			

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary congestion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary fistula				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary haemorrhage				
subjects affected / exposed	1 / 1 (100.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Delirium				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Blood bilirubin increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatine phosphokinase MB increased				
subjects affected / exposed	0 / 1 (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 / 1 (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 / 1 (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 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram ST segment elevation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram T wave inversion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Platelet count decreased				
subjects affected / exposed	1 / 1 (100.00%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Troponin I increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Troponin T increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural				

complications				
Fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon rupture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute myocardial infarction				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cardiogenic shock				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebrovascular accident				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuralgia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Somnolence				

subjects affected / exposed	0 / 1 (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 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 1 (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 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Eye haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uveitis			
subjects affected / exposed	0 / 1 (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 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal haemorrhage				

subjects affected / exposed	0 / 1 (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 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Biliary obstruction				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Dermatitis acneiform				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pruritus				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin necrosis				

subjects affected / exposed	0 / 1 (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 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder dilatation			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 1 (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 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis of jaw			
subjects affected / exposed	0 / 1 (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 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in jaw				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abdominal infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dacryocystitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic infection				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis pneumococcal				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periorbital cellulitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal cord infection				
subjects affected / exposed	0 / 1 (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 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				

subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypophosphataemia			
subjects affected / exposed	0 / 1 (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	Phase Ia - Schedule A: 0.2 mg BI 894999	Phase Ia - Schedule A: 1 mg BI 894999	Phase Ia - Schedule A: 1.5 mg BI 894999
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	3 / 3 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
Haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	2 / 2 (100.00%)	3 / 3 (100.00%)	4 / 6 (66.67%)
occurrences (all)	2	3	4
Facial pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Iodine allergy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Heavy menstrual bleeding			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Testicular pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 2 (100.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Laryngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Rhinorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2

Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Personality change			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone			

decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Echocardiogram abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Prothrombin level decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Troponin increased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Overdose			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Subcutaneous haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract stoma complication			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Ventricular arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Agnosia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Motor dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Coagulopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Lymph node haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	0	2	3
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis erosive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Lip dry			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	5
Subileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	5	1
Hepatobiliary disorders			
Cholangitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis psoriasiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Prurigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pubic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oesophageal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Tracheitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	3 / 6 (50.00%)
occurrences (all)	1	1	3
Cell death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Malnutrition			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ia - Schedule A: 2 mg BI 894999	Phase Ia - Schedule C: 6/3 mg BI 894999	Phase Ia - Schedule B: 1.5 mg BI 894999
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	15 / 15 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pallor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	4 / 6 (66.67%)	8 / 15 (53.33%)	1 / 6 (16.67%)
occurrences (all)	5	10	1
Facial pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Generalised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypothermia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Iodine allergy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	0 / 6 (0.00%)	3 / 15 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Laryngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	2 / 15 (13.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 15 (13.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Hallucination			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Personality change			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 15 (13.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	2 / 6 (33.33%)	1 / 15 (6.67%)	1 / 6 (16.67%)
occurrences (all)	2	2	3
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood magnesium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

C-reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Echocardiogram abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 15 (13.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Neutrophil count decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Prothrombin level decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Troponin I increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	2 / 6 (33.33%)	1 / 15 (6.67%)	1 / 6 (16.67%)
occurrences (all)	4	2	1
Troponin increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Urine output decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Subcutaneous haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract stoma complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Agnosia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Amnesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dizziness postural			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	2 / 6 (33.33%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Motor dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	5 / 15 (33.33%)	2 / 6 (33.33%)
occurrences (all)	1	7	4
Coagulopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymph node haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	5 / 6 (83.33%)	8 / 15 (53.33%)	0 / 6 (0.00%)
occurrences (all)	8	10	0
Ear and labyrinth disorders			
Ear congestion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Abdominal distension			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 6 (16.67%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	8 / 15 (53.33%)	3 / 6 (50.00%)
occurrences (all)	0	9	3
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Flatulence			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis erosive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 6 (33.33%)	4 / 15 (26.67%)	4 / 6 (66.67%)
occurrences (all)	3	4	5
Odynophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retching			

subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Subileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	3 / 15 (20.00%)	3 / 6 (50.00%)
occurrences (all)	1	3	6
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis psoriasiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Intertrigo			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prurigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 6 (16.67%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bone pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pubic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bronchitis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile colitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Diverticulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oesophageal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rash pustular			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Mucosal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	4 / 15 (26.67%)	1 / 6 (16.67%)
occurrences (all)	2	4	1
Cell death			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dehydration			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 15 (13.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Hyperphosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	3 / 15 (20.00%)	1 / 6 (16.67%)
occurrences (all)	1	4	1
Hypomagnesaemia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 15 (13.33%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
Hyponatraemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 15 (6.67%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Malnutrition			
subjects affected / exposed	0 / 6 (0.00%)	0 / 15 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ia - Schedule B: 2 mg BI 894999	Phase Ia - Schedule B: 2.5 mg BI 894999	Phase Ia - Schedule C: 5/2.5 mg BI 894999
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	12 / 13 (92.31%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	1 / 6 (16.67%)	2 / 13 (15.38%)	2 / 4 (50.00%)
occurrences (all)	3	2	2
Haematoma			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Chest discomfort			

subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 6 (50.00%)	6 / 13 (46.15%)	2 / 4 (50.00%)
occurrences (all)	4	10	4
Facial pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypothermia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	3 / 13 (23.08%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 13 (15.38%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iodine allergy			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Testicular pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Cough			
subjects affected / exposed	1 / 6 (16.67%)	3 / 13 (23.08%)	1 / 4 (25.00%)
occurrences (all)	1	4	1
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)	5 / 13 (38.46%)	1 / 4 (25.00%)
occurrences (all)	2	5	1
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hallucination			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Personality change			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood antidiuretic hormone			

decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 13 (7.69%)	1 / 4 (25.00%)
occurrences (all)	4	1	1
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Echocardiogram abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			

subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Prothrombin level decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	1 / 6 (16.67%)	2 / 13 (15.38%)	2 / 4 (50.00%)
occurrences (all)	1	2	3
Troponin increased			

subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urine output decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 13 (7.69%)	2 / 4 (50.00%)
occurrences (all)	1	1	2
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Post procedural haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Subcutaneous haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tooth fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract stoma complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Angina pectoris			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Ventricular arrhythmia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Agnosia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dizziness postural			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 6 (16.67%)	3 / 13 (23.08%)	1 / 4 (25.00%)
occurrences (all)	1	5	1
Dysgeusia			
subjects affected / exposed	2 / 6 (33.33%)	3 / 13 (23.08%)	2 / 4 (50.00%)
occurrences (all)	2	3	2
Motor dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Radiculopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Taste disorder			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 6 (33.33%)	4 / 13 (30.77%)	0 / 4 (0.00%)
occurrences (all)	3	4	0
Coagulopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Lymph node haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 13 (23.08%)	0 / 4 (0.00%)
occurrences (all)	0	10	0
Lymphopenia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Thrombocytopenia			
subjects affected / exposed	3 / 6 (50.00%)	6 / 13 (46.15%)	2 / 4 (50.00%)
occurrences (all)	3	10	4
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ear haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Anal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Angular cheilitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Diarrhoea			
subjects affected / exposed	2 / 6 (33.33%)	6 / 13 (46.15%)	3 / 4 (75.00%)
occurrences (all)	2	9	5
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	3 / 13 (23.08%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis erosive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Lip dry			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	2 / 6 (33.33%)	2 / 13 (15.38%)	1 / 4 (25.00%)
occurrences (all)	2	2	3
Odynophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Retching			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Subileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)	1 / 13 (7.69%)	1 / 4 (25.00%)
occurrences (all)	5	1	2
Hepatobiliary disorders			
Cholangitis			

subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hepatic cytolysis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hepatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis psoriasiform			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dermatitis acneiform			
subjects affected / exposed	1 / 6 (16.67%)	2 / 13 (15.38%)	1 / 4 (25.00%)
occurrences (all)	1	3	1
Dry skin			
subjects affected / exposed	1 / 6 (16.67%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Intertrigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Prurigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Psoriasis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	3 / 13 (23.08%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Myalgia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Pubic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Bronchitis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Genital infection fungal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Impetigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Oesophageal infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection bacterial			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Mucosal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)	4 / 13 (30.77%)	1 / 4 (25.00%)
occurrences (all)	2	4	2
Cell death			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fluid retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gout			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Hyperphosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	3 / 6 (50.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	5	1	0
Malnutrition			
subjects affected / exposed	0 / 6 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Phase Ia - Schedule A: 0.5 mg BI 89499	Phase Ia - Schedule A: 5 mg BI 894999	Phase Ia - Schedule C: 7/3.5 mg BI 894999
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	2 / 2 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	3 / 12 (25.00%)
occurrences (all)	1	0	3
Haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pallor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	2 / 2 (100.00%)	10 / 12 (83.33%)
occurrences (all)	1	4	11
Facial pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Chills			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Iodine allergy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oedema genital			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Perineal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Scrotal oedema			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Testicular pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	3 / 12 (25.00%)
occurrences (all)	1	0	5
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Laryngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Rhinorrhoea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Personality change			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood antidiuretic hormone decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

C-reactive protein increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Echocardiogram abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	3 / 12 (25.00%)
occurrences (all)	0	1	3
Neutrophil count decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Prothrombin level decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Troponin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Infusion related reaction			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Muscle rupture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Subcutaneous haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract stoma complication			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Agnosia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	2 / 12 (16.67%)
occurrences (all)	3	2	2
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	3 / 12 (25.00%)
occurrences (all)	0	1	3
Motor dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Radiculopathy			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Somnolence			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sciatica			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Taste disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	6 / 12 (50.00%)
occurrences (all)	1	0	8
Coagulopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	7 / 12 (58.33%)
occurrences (all)	0	1	20
Ear and labyrinth disorders			
Ear congestion			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vitreous haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	2
Abdominal distension			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	4 / 12 (33.33%)
occurrences (all)	1	1	4
Diarrhoea			
subjects affected / exposed	1 / 2 (50.00%)	2 / 2 (100.00%)	3 / 12 (25.00%)
occurrences (all)	1	3	6
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	4 / 12 (33.33%)
occurrences (all)	0	0	4
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastritis erosive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	6 / 12 (50.00%)
occurrences (all)	2	0	7
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Retching			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	2 / 2 (100.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Subileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	4 / 12 (33.33%)
occurrences (all)	1	0	5
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis psoriasiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Intertrigo			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Prurigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Psoriasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Bone pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Pubic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oesophageal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Tooth abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Mucosal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	2 / 2 (100.00%)	6 / 12 (50.00%)
occurrences (all)	1	3	7
Cell death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dehydration			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	3
Hyperphosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 2 (100.00%)	1 / 12 (8.33%)
occurrences (all)	0	3	1
Malnutrition			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ia - Schedule B: 1.5 mg BI 894999 (DLBCL patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (SCLC patients)	Phase Ia - Schedule C: BI 894999 5/2.5 mg (DLBCL patients)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	3 / 3 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Chest discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	3	0	1
Chest pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Facial pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	3	0	1
Peripheral swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iodine allergy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Testicular pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 8 (12.50%)	2 / 3 (66.67%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Dyspnoea			
subjects affected / exposed	1 / 8 (12.50%)	2 / 3 (66.67%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Laryngeal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pleuritic pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Personality change			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood antidiuretic hormone			

decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Cortisol increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Echocardiogram abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Prothrombin level decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Troponin T increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Troponin increased			

subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	3	0	1
Urine output decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Subcutaneous haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract stoma complication			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Ventricular arrhythmia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Agnosia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	2
Motor dysfunction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	1	1	3
Coagulopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Lymph node haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lymph node pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Neutropenia			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	2 / 2 (100.00%)
occurrences (all)	3	0	3
Lymphopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	4 / 8 (50.00%)	2 / 3 (66.67%)	1 / 2 (50.00%)
occurrences (all)	4	2	2
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	2 / 2 (100.00%)
occurrences (all)	3	0	5
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis erosive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Lip dry			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Odynophagia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Oral mucosal erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Subileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Hepatobiliary disorders			
Cholangitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hepatic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis psoriasiform			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	2 / 2 (100.00%)
occurrences (all)	1	0	2
Intertrigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Prurigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Urinary tract pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	2	0	1
Myalgia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Pubic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Bronchitis viral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oesophageal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1

Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Cell death			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Folate deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Hypophosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Malnutrition			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ia - Schedule C: 4/2 mg BI 894999 (DLBCL patients	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)	Phase Ia - Schedule B: 2.5 mg BI 894999 (DLBCL patients)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	2 / 2 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 2 (0.00%)	2 / 2 (100.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Orthostatic hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	3 / 4 (75.00%)
occurrences (all)	1	1	5
Facial pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Iodine allergy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cough			

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Laryngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Personality change			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

C-reactive protein increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Echocardiogram abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Neutrophil count decreased			

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	8	0
Platelet count decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Prothrombin level decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Troponin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	7	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Face injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subcutaneous haematoma			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin laceration			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tongue injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urinary tract stoma complication			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Agnosia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Motor dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Radiculopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Coagulopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymph node haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 2 (100.00%)	4 / 4 (100.00%)
occurrences (all)	0	8	9
Ear and labyrinth disorders			
Ear congestion			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Abdominal distension			

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Anal fissure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 2 (100.00%)	2 / 2 (100.00%)	3 / 4 (75.00%)
occurrences (all)	3	2	3
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis erosive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	2 / 4 (50.00%)
occurrences (all)	1	1	3
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retching			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis psoriasiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intertrigo			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prurigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Psoriasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Bone pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pubic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Erysipelas			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Tooth abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Mucosal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 2 (100.00%)	1 / 2 (50.00%)	2 / 4 (50.00%)
occurrences (all)	3	1	2
Cell death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dehydration			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ib - Schedule B: 2 mg BI 894999 (SCLC patients)	Phase Ib - Schedule C: BI 894999 6/3 mg (NC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (NC patients)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	21 / 21 (100.00%)	20 / 20 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 9 (0.00%)	2 / 21 (9.52%)	2 / 20 (10.00%)
occurrences (all)	0	3	3
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	4 / 21 (19.05%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
Haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Chest discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 21 (9.52%)	1 / 20 (5.00%)
occurrences (all)	1	3	1
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Fatigue			
subjects affected / exposed	3 / 9 (33.33%)	10 / 21 (47.62%)	8 / 20 (40.00%)
occurrences (all)	3	14	11
Facial pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 9 (11.11%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	1	3	0

Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	5 / 21 (23.81%)	4 / 20 (20.00%)
occurrences (all)	0	6	7
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Iodine allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Perineal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Testicular pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	3 / 9 (33.33%)	5 / 21 (23.81%)	2 / 20 (10.00%)
occurrences (all)	3	7	2
Dyspnoea			
subjects affected / exposed	4 / 9 (44.44%)	1 / 21 (4.76%)	3 / 20 (15.00%)
occurrences (all)	5	1	4
Dyspnoea exertional			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	4 / 21 (19.05%)	2 / 20 (10.00%)
occurrences (all)	0	5	2
Laryngeal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	1 / 9 (11.11%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Nasal discomfort			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Pharyngeal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	4 / 20 (20.00%)
occurrences (all)	0	0	4

Confusional state			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Hallucination			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Personality change			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 9 (22.22%)	4 / 21 (19.05%)	6 / 20 (30.00%)
occurrences (all)	2	7	8
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 21 (4.76%)	5 / 20 (25.00%)
occurrences (all)	1	3	6
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	2 / 20 (10.00%)
occurrences (all)	0	2	2
Blood antidiuretic hormone			

decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	5
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	5 / 20 (25.00%)
occurrences (all)	1	0	5
Blood creatinine increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Blood magnesium decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Blood glucose increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Echocardiogram abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Ejection fraction decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	5 / 20 (25.00%)
occurrences (all)	0	1	8
Lymphocyte count decreased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	1 / 9 (11.11%)	8 / 21 (38.10%)	8 / 20 (40.00%)
occurrences (all)	3	13	14
Prothrombin level decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Troponin T increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	5 / 20 (25.00%)
occurrences (all)	0	2	6
Troponin increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 9 (11.11%)	3 / 21 (14.29%)	0 / 20 (0.00%)
occurrences (all)	1	3	0
White blood cell count decreased			
subjects affected / exposed	0 / 9 (0.00%)	2 / 21 (9.52%)	4 / 20 (20.00%)
occurrences (all)	0	6	6
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Face injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Muscle rupture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Subcutaneous haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary tract stoma complication			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Angina pectoris			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Sinus tachycardia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 21 (9.52%)	2 / 20 (10.00%)
occurrences (all)	1	2	2

Ventricular arrhythmia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Agnosia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
Dizziness postural			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 9 (0.00%)	2 / 21 (9.52%)	3 / 20 (15.00%)
occurrences (all)	0	4	4
Dysgeusia			
subjects affected / exposed	3 / 9 (33.33%)	3 / 21 (14.29%)	4 / 20 (20.00%)
occurrences (all)	3	4	5
Motor dysfunction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Radiculopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)	6 / 21 (28.57%)	11 / 20 (55.00%)
occurrences (all)	0	10	18
Coagulopathy			
subjects affected / exposed	0 / 9 (0.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Eosinophilia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Lymph node haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	3
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 9 (22.22%)	5 / 21 (23.81%)	5 / 20 (25.00%)
occurrences (all)	2	5	20
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	4 / 21 (19.05%)	1 / 20 (5.00%)
occurrences (all)	1	5	1
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Anal fissure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Ascites			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 9 (0.00%)	4 / 21 (19.05%)	5 / 20 (25.00%)
occurrences (all)	0	4	5
Diarrhoea			
subjects affected / exposed	3 / 9 (33.33%)	9 / 21 (42.86%)	4 / 20 (20.00%)
occurrences (all)	4	17	7
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
Flatulence			
subjects affected / exposed	0 / 9 (0.00%)	3 / 21 (14.29%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
Gastritis			
subjects affected / exposed	1 / 9 (11.11%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Gastritis erosive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Lip dry			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 9 (11.11%)	4 / 21 (19.05%)	4 / 20 (20.00%)
occurrences (all)	1	5	4
Odynophagia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Oral mucosal erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Subileus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 9 (22.22%)	3 / 21 (14.29%)	1 / 20 (5.00%)
occurrences (all)	3	3	1
Hepatobiliary disorders			
Cholangitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis psoriasiform			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Dry skin			
subjects affected / exposed	0 / 9 (0.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Intertrigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	3
Eczema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Prurigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	0 / 9 (0.00%)	2 / 21 (9.52%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
Psoriasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	1 / 9 (11.11%)	3 / 21 (14.29%)	2 / 20 (10.00%)
occurrences (all)	1	3	2
Purpura			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 9 (0.00%)	3 / 21 (14.29%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 9 (11.11%)	4 / 21 (19.05%)	2 / 20 (10.00%)
occurrences (all)	1	4	2
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	3 / 21 (14.29%)	3 / 20 (15.00%)
occurrences (all)	0	4	4
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Myalgia			

subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Pubic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Bronchitis viral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Oesophageal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Rash pustular			
subjects affected / exposed	0 / 9 (0.00%)	2 / 21 (9.52%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed	2 / 9 (22.22%)	3 / 21 (14.29%)	5 / 20 (25.00%)
occurrences (all)	4	3	5
Cell death			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	1 / 9 (11.11%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	4 / 21 (19.05%)	2 / 20 (10.00%)
occurrences (all)	0	4	3
Hyperkalaemia			

subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	4 / 20 (20.00%)
occurrences (all)	0	0	6
Hyperphosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	2 / 20 (10.00%)
occurrences (all)	0	2	4
Hypoalbuminaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	4 / 20 (20.00%)
occurrences (all)	0	2	11
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	5
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	4 / 21 (19.05%)	3 / 20 (15.00%)
occurrences (all)	0	7	5
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	4 / 20 (20.00%)
occurrences (all)	0	1	4
Hyponatraemia			
subjects affected / exposed	1 / 9 (11.11%)	5 / 21 (23.81%)	8 / 20 (40.00%)
occurrences (all)	1	7	15
Hypophosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 21 (4.76%)	3 / 20 (15.00%)
occurrences (all)	0	1	4
Malnutrition			
subjects affected / exposed	0 / 9 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ib - Schedule B: 2 mg BI 894999 (mCRPC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (mCRPC patients)	Phase Ib - Schedule B: 2.5 mg BI 894999 (CRC patients)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	10 / 10 (100.00%)	14 / 14 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	0	2	2
Haematoma			
subjects affected / exposed	1 / 1 (100.00%)	1 / 10 (10.00%)	2 / 14 (14.29%)
occurrences (all)	1	1	2
Orthostatic hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	2 / 14 (14.29%)
occurrences (all)	0	1	3
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	6 / 10 (60.00%)	6 / 14 (42.86%)
occurrences (all)	0	9	8
Facial pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypothermia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	3 / 10 (30.00%)	1 / 14 (7.14%)
occurrences (all)	0	5	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Iodine allergy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Cough			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	3 / 14 (21.43%)
occurrences (all)	0	1	3
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	4 / 10 (40.00%)	3 / 14 (21.43%)
occurrences (all)	0	6	5
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 1 (100.00%)	2 / 10 (20.00%)	1 / 14 (7.14%)
occurrences (all)	1	2	1
Laryngeal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Agitation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Depression			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Personality change			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Blood antidiuretic hormone decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Blood magnesium decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

C-reactive protein increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cortisol increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Echocardiogram abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 1 (100.00%)	2 / 10 (20.00%)	1 / 14 (7.14%)
occurrences (all)	1	2	1
Prothrombin level decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Troponin increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Urine output decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	4 / 10 (40.00%)	1 / 14 (7.14%)
occurrences (all)	0	5	1
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Muscle rupture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Subcutaneous haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary tract stoma complication			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Agnosia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Cauda equina syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Disturbance in attention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	4 / 10 (40.00%)	3 / 14 (21.43%)
occurrences (all)	0	5	3
Motor dysfunction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1 (100.00%)	9 / 10 (90.00%)	3 / 14 (21.43%)
occurrences (all)	4	15	4
Coagulopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymph node haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	5 / 10 (50.00%)	5 / 14 (35.71%)
occurrences (all)	0	11	9
Ear and labyrinth disorders			
Ear congestion			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Periorbital oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	6
Abdominal distension			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Anal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	3 / 10 (30.00%)	3 / 14 (21.43%)
occurrences (all)	0	3	3
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	6 / 10 (60.00%)	8 / 14 (57.14%)
occurrences (all)	0	8	16
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flatulence			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastritis erosive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	5 / 10 (50.00%)	6 / 14 (42.86%)
occurrences (all)	0	5	11
Odynophagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Retching			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 1 (100.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Subileus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	6 / 10 (60.00%)	3 / 14 (21.43%)
occurrences (all)	0	6	7
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis psoriasiform			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Intertrigo			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Macule			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Prurigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Psoriasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 1 (100.00%)	3 / 10 (30.00%)	2 / 14 (14.29%)
occurrences (all)	1	4	2
Pollakiuria			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Urinary tract pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	3
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Bone pain			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pubic pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Clostridial infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Herpes zoster			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oesophageal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Tooth abscess			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Mucosal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 1 (100.00%)	6 / 10 (60.00%)	7 / 14 (50.00%)
occurrences (all)	1	8	8
Cell death			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dehydration			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hyperphosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Malnutrition			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase Ib - Schedule C: BI 894999 7/3.5 mg (NC patients)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Orthostatic hypotension			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Pallor			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chest discomfort			

subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Asthenia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Chest pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Fatigue				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Facial pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Chills				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Gait disturbance				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
General physical health deterioration				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Generalised oedema				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Malaise				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Hypothermia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Oedema peripheral				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Non-cardiac chest pain				

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Iodine allergy			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Heavy menstrual bleeding			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Oedema genital			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Perineal pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Scrotal oedema			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Testicular pain			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Vulvovaginal discomfort			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Laryngeal inflammation			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Nasal discomfort			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Pharyngeal inflammation			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Pleuritic pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Respiratory tract congestion			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Agitation			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		

Confusional state			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hallucination			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Personality change			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	2		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Blood antidiuretic hormone			

decreased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Blood bilirubin increased				
subjects affected / exposed	1 / 1 (100.00%)			
occurrences (all)	2			
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Blood creatinine increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Blood magnesium decreased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Blood glucose increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
C-reactive protein increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Cardiac murmur				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Cortisol increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Echocardiogram abnormal				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Electrocardiogram PR prolongation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Ejection fraction decreased				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Electrocardiogram ST segment elevation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Electrocardiogram T wave inversion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
International normalised ratio increased				
subjects affected / exposed	1 / 1 (100.00%)			
occurrences (all)	1			
Lymphocyte count decreased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Neutrophil count decreased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Platelet count decreased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Prothrombin level decreased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Troponin I increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Troponin T increased				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Troponin increased				

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Urine output decreased			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Face injury			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Limb injury			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Muscle rupture			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Overdose			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Post procedural haematoma			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Skin abrasion			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Subcutaneous haematoma			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Skin laceration			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Tongue injury			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Tooth fracture			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Urinary tract stoma complication			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Angina pectoris			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		

Ventricular arrhythmia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Agnosia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Amnesia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Cauda equina syndrome			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Disturbance in attention			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dizziness postural			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Motor dysfunction			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Radiculopathy			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Taste disorder			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Coagulopathy			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Eosinophilia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		

Lymph node haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Lymph node pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Ear haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dry eye			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Vitreous haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Periorbital oedema			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Anal fissure			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Anal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Aphthous ulcer			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Angular cheilitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Anal inflammation			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		

Ascites				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Dry mouth				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	1 / 1 (100.00%)			
occurrences (all)	1			
Flatulence				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Gastritis erosive				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Gastrointestinal disorder				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Haemorrhoids				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			

Lip dry subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Melaena subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Lower gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Nausea subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Odynophagia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Oral mucosal erythema subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Retching subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Stomatitis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Subileus subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Toothache subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Hepatobiliary disorders Cholangitis			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hepatic cytolysis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hepatic pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dermatitis psoriasiform			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dermatitis acneiform			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Intertrigo			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Macule			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Prurigo			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		

Pruritus			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Psoriasis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Skin ulcer			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Purpura			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Urinary tract pain			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Bone pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Myalgia			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Pubic pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Bronchitis viral			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Clostridial infection			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Erysipelas			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Diverticulitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		

Gastroenteritis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Escherichia urinary tract infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Genital herpes simplex				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Genital infection fungal				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Herpes dermatitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Herpes zoster				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Oesophageal infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			

Pharyngitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Rash pustular				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Respiratory tract infection bacterial				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Tooth abscess				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Tooth infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Tracheitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			
Urinary tract infection enterococcal				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences (all)	0			

Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Mucosal infection			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Stoma site infection			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Cell death			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Fluid retention			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Folate deficiency			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Gout			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hyperphosphataemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Malnutrition			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 September 2015	1st global protocol amendment: The potential Cytochrome P450 (CYP) inducing effect was addressed in the amended Clinical Trial Protocol (CTP) and a non-exhaustive list of CYP 3A4, 2C8 and 1A2 substrates was added (Section 10.6 of the CTP). Furthermore, it was added to inclusion criterion 6 that an additional barrier method is necessary for women of childbearing potential using a contraceptive pill due to the potential CYP3A4 inducing effect of BI 894999.
08 April 2016	2nd global protocol amendment: A second dosing schedule (Schedule B: 3-week cycles [21 days] with 2 weeks on treatment and 1 week off treatment) was introduced. The evaluation of BI 894999 (Schedule A: continuous dosing in 3-week cycles) in patients with Non-Hodgkin Lymphoma (NHL) was initiated. The secondary pharmacokinetics (PK) endpoints were reduced, and some secondary PK parameters were re-defined as further endpoints.
23 November 2016	3rd global protocol amendment: Precautionary measures were introduced because of cardiac findings in patients participating in the trial. The measures were applicable to all ongoing patients who had benefited from the treatment in order to allow them to continue the treatment under close cardiac safety monitoring. Further enrolment into the trial was stopped.
12 May 2017	4th global protocol amendment: External cardiologists concluded that the cause of the troponin elevation was unclear. Patients could continue on treatment with appropriate monitoring. Cardiac monitoring was adapted. Patients in the NHL cohort were be treated with the Schedule selected by the Data Monitoring Committee (DMC) once Maximum Tolerated dose (MTD) had been determined for both Schedules A and B in patients with solid tumours. The Dose Limiting Toxicity (DLT) definition was revised.
18 October 2017	5th global protocol amendment: Changes were introduced to restrict the definition of NHL to allow analyses of results in a more homogenous population. The NHL cohort was restricted to DLBCL patients. The protocol was amended to reflect the selection of 4 types of solid tumours (SCLC, mCRPC, CRC and NC) to be tested in the Phase 1b part of the study.
25 June 2018	6th global protocol amendment: The protocol was revised to clarify the significance of drug-related troponin Common Terminology Criteria for Adverse Events (CTCAE) grade 3.
05 September 2018	7th global protocol amendment: NC allowed inclusion of minor patients (aged ≥15 years at the time of consent). The NC cohort was also extended to up to 20 patients. NC patients who were progressing under trial treatment could continue with treatment if they derived clinical benefit and no other treatment option was available.
05 November 2018	8th global protocol amendment: Included clarifications and changes for consistency that were introduced following review of protocol version 7.0 by the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) authority in Germany and of protocol version 8.0 by the U.S. Food and Drug Administration (US FDA).
05 February 2019	9th global protocol amendment: A third intermittent dose escalation was added (Schedule C) in Phase Ia.

24 September 2019	10th global protocol amendment: If Schedule C appeared to have a better tolerability in patients with solid tumours than Schedule B, this could be extended to NC patients. Overall survival was added as an endpoint for patients with NC. Time to treatment failure was also added as an endpoint. Eligibility criteria were revised for including patients with NC due to their likely fast progression and the lack of any other treatment options in this indication. NC patients who had a mixed radiological response to treatment could remain on treatment if they derived clinical benefit.
24 June 2020	11th global protocol amendment: Due to the COVID-19 pandemic, the protocol was adapted to minimise in-patient visits.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
04 October 2016	On 04 Oct 2016, the sponsor decided to put a temporary hold on further recruitment of patients in trial 1367.1. The measure was taken since review of patient data revealed some patients with increased troponin levels. A thorough review by cardiologists was initiated with regards to troponin levels, Electrocardiogram (ECG), and clinical summaries of all enrolled patients. Evidence supporting a causal association between the increased laboratory troponin values and the administration of the trial medication could not be established. There were no corresponding clinically significant findings based on the reviewed ECGs and the clinical summaries of enrolled patients. The external review concluded that the cause of troponin elevation may be multifactorial in the trial patient population. In conclusion, the findings were considered to not preclude further clinical development. Consequently, patient recruitment was re-started on 25-April-2017. Ongoing patients continued the treatment during the time that recruitment was put on hold.	25 April 2017

Notes:

Limitations and caveats

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

This trial was closed in accordance with protocol-defined criteria for stopping the trial following assessments of futility. Trial was completed as described in protocol.

Notes: