Clinical trial results:
A Phase 1 Dose Escalation and Phase 2 Randomized Double-Blind Study of Veliparib in Combination with Carboplatin and Etoposide as a Therapy of Treatment-Naïve Extensive Stage Disease Small Cell Lung Cancer

Summary

EudraCT number	2014-001764-35
Trial protocol	ES NL CZ BE HU FR
Global end of trial date	17 April 2019

Results information

Result version number	v2 (current)
This version publication date	22 May 2020
First version publication date	30 April 2020
Version creation reason	• Correction of full data set Need to correct a table in the safety section of the report.

Trial information

Trial identification

Sponsor protocol code	M14-361

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02289690
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Abbvie Deutschland GmbH & Co.KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Maidenhead, Berkshire, United Kingdom, SL6-4UB
Public contact	Global Medical Services, AbbVie, 011 800-633-9110,
Scientific contact	Bruce Bach, MD, AbbVie, bruce.bach@abbvie.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	17 April 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 April 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the Phase 1 dose-escalation were:
- To establish the maximum tolerated dose (MTD) and to establish the recommended Phase 2 dose (RPTD) and schedule for veliparib in combination with carboplatin and etoposide.
- To evaluate the pharmacokinetic (PK) interaction between veliparib and etoposide.
The primary objective of Phase 2 was:
- To evaluate if veliparib in combination with carboplatin and etoposide followed by veliparib maintenance monotherapy results in improved progression-free survival vs. placebo in combination with carboplatin and etoposide followed by placebo monotherapy in subjects with treatment-naïve extensive stage small-cell lung cancer (ED SCLC).

Protection of trial subjects:

All subjects entering the study had to sign an informed consent that was explained to them and questions encouraged.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 October 2014
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	Spain: 24
Country: Number of subjects enrolled	United States: 44
Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Belgium: 12
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Czech Republic: 6
Country: Number of subjects enrolled	France: 10
Country: Number of subjects enrolled	Hungary: 24
Country: Number of subjects enrolled	Korea, Republic of: 17
Country: Number of subjects enrolled	Netherlands: 36
Country: Number of subjects enrolled	Romania: 1
Country: Number of subjects enrolled	Russian Federation: 41
Worldwide total number of subjects	221
EEA total number of subjects	113

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)	131
From 65 to 84 years	88
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 52 study sites located in 12 countries (Australia, Belgium, Canada, Czech Republic, France, Hungary, Korea, the Netherlands, Romania, Russian Federation, Spain, United States).

Pre-assignment

Screening details:

Participants in Phase 1 were sequentially assigned to ascending dose levels of veliparib in combination with standard carboplatin/etoposide regimen. Participants in Phase 2 were randomized equally to placebo, carboplatin/etoposide followed by placebo maintenance, or to veliparib, carboplatin/etoposide followed by veliparib or placebo maintenance.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Blinding implementation details:

Phase 1 was open-label. Participants in Phase 2 were randomized using an Interactive Response Technology (IRT) system. All study site personnel, including the investigator, study coordinator, as well as the subjects, remained blinded to the treatment throughout the course of the Phase 2 portion of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide

Arm description:

Participants received 80 mg veliparib orally twice a day (BID) on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered intravenously (IV) on Day 1 at a target area under the curve (AUC) 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Veliparib
Investigational medicinal product code	ABT-888
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsules administered orally twice a day according to the dosing schedule.

Arm title	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide

Arm description:

Participants received 120 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Arm type	Experimental

Investigational medicinal product name	Veliparib
Investigational medicinal product code	ABT-888
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsules administered orally twice a day according to the dosing schedule.

Arm title	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide

Arm description:

Participants received 160 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

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

Dosage and administration details:

Capsules administered orally twice a day according to the dosing schedule.

Arm title	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide

Arm description:

Participants received 200 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Veliparib
Investigational medicinal product code	ABT-888
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsules administered orally twice a day according to the dosing schedule.

Arm title	Phase 1: Veliparib 240 mg BID 7 Days + Carboplatin/Etoposide

Arm description:

Participants received 240 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Arm type	Experimental

Investigational medicinal product name	Veliparib
Investigational medicinal product code	ABT-888
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsules administered orally twice a day according to the dosing schedule.

Arm title	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide

Arm description:

Participants received 240 mg veliparib orally BID on Days -2 to 12 (14 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 12 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Veliparib
Investigational medicinal product code	ABT-888
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsules administered orally twice a day according to the dosing schedule.

Arm title	Phase 1: Veliparib 240 mg BID 21 Days + Carboplatin/Etoposide

Arm description:

Participants received 240 mg veliparib orally BID on Days -2 to Day 19 (continuous schedule) in combination with carboplatin/etoposide for up to four 21-day cycles. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Veliparib
Investigational medicinal product code	ABT-888
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsules administered orally twice a day according to the dosing schedule.

Arm title	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib

Arm description:

Participants in Arm A received veliparib 240 mg BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min administered on Day 1, and etoposide 100 mg/m² administered on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Veliparib
Investigational medicinal product code	ABT-888
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Veliparib capsules administered orally twice a day according to the dosing schedule.

Arm title	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo

Arm description:

Participants In Arm B received veliparib 240 mg BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min administered on Day 1, and etoposide 100 mg/m² administered on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression received placebo monotherapy BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Veliparib
Investigational medicinal product code	ABT-888
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Veliparib capsules administered orally twice a day according to the dosing schedule.

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

Dosage and administration details:

Placebo capsules administered orally twice a day according to the dosing schedule.

Arm title	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo

Arm description:

Participants in Arm C received placebo BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min on Day 1, and etoposide 100 mg/m² on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression received placebo monotherapy BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Arm type	Active comparator
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo capsules administered orally twice a day according to the dosing schedule.

Number of subjects in period 1	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide
Started	4	3	4
Received Study Drug	4	3	4

Completed	0	0	0
Not completed	4	3	4
Adverse Event Related to Progression	-	1	1
Consent withdrawn by subject	1	-	-
Other	-	-	-
Death	-	-	-
Sponsor Discontinued Study	-	-	-
Progressive Disease, Per Protocol	3	2	3
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide
Started	3	8	14
Received Study Drug	3	8	14
Completed	0	0	0
Not completed	3	8	14
Adverse Event Related to Progression	-	1	-
Consent withdrawn by subject	-	1	1
Other	1	1	-
Death	-	-	-
Sponsor Discontinued Study	-	-	-
Progressive Disease, Per Protocol	2	5	13
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1: Veliparib 240 mg BID 21 Days + Carboplatin/Etoposide	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo
Started	4	61	59
Received Study Drug	4	60	58
Completed	0	0	0
Not completed	4	61	59
Adverse Event Related to Progression	1	-	-
Consent withdrawn by subject	-	-	4
Other	1	2	3
Death	-	49	45
Sponsor Discontinued Study	-	9	7
Progressive Disease, Per Protocol	2	-	-
Lost to follow-up	-	1	-

Number of subjects in period 1	Phase 2: Placebo + Carboplatin/Etoposid

	e -> Placebo
Started	61
Received Study Drug	60
Completed	0
Not completed	61
Adverse Event Related to Progression	-
Consent withdrawn by subject	2
Other	1
Death	41
Sponsor Discontinued Study	15
Progressive Disease, Per Protocol	-
Lost to follow-up	2

Baseline characteristics

Reporting groups

Reporting group title	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 80 mg veliparib orally twice a day (BID) on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered intravenously (IV) on Day 1 at a target area under the curve (AUC) 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 120 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 160 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 200 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 240 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 240 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 240 mg veliparib orally BID on Days -2 to 12 (14 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 12 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 240 mg BID 21 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 240 mg veliparib orally BID on Days -2 to Day 19 (continuous schedule) in combination with carboplatin/etoposide for up to four 21-day cycles. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib

Reporting group description:

Participants in Arm A received veliparib 240 mg BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min administered on Day 1, and etoposide 100 mg/m² administered on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo

Reporting group description:

Participants In Arm B received veliparib 240 mg BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min administered on Day 1, and etoposide 100 mg/m² administered on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression received placebo monotherapy BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo

Reporting group description:

Participants in Arm C received placebo BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min on Day 1, and etoposide 100 mg/m² on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression received placebo monotherapy BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide
Number of subjects	4	3	4
Age categorical Units: Subjects			
Age continuous Units: years			
median	74.0	69.0	62.5
full range (min-max)	55.0 to 79.0	62.0 to 75.0	56.0 to 74.0
Gender categorical Units: Subjects			
Female	3	0	2
Male	1	3	2
Race Units: Subjects			
White	4	3	4
Black or African American	0	0	0
Asian	0	0	0
Missing	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status			
Measure Description: ECOG performance status is used by doctors and researchers to assess how a participant's disease is progressing, assess how the disease affects the daily living activities of the participant and determine appropriate treatment and prognosis. 0 = Fully Active (Most Favorable Activity);			

1 = Restricted activity but ambulatory; 2 = Ambulatory but unable to carry out work activities; 3 = Limited Self-Care; 4 = Completely Disabled, No self-care (Least Favorable Activity)			
Units: Subjects			
0 - Fully active	1	1	1
1 - Restricted but ambulatory	3	2	3
Missing	0	0	0

Reporting group values	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide
Number of subjects	3	8	14
Age categorical Units: Subjects			
Age continuous Units: years			
median	54.0	52.0	66.0
full range (min-max)	52.0 to 68.0	43.0 to 63.0	52.0 to 72.0
Gender categorical Units: Subjects			
Female	1	2	5
Male	2	6	9
Race Units: Subjects			
White	3	8	14
Black or African American	0	0	0
Asian	0	0	0
Missing	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status			
Measure Description: ECOG performance status is used by doctors and researchers to assess how a participant's disease is progressing, assess how the disease affects the daily living activities of the participant and determine appropriate treatment and prognosis. 0 = Fully Active (Most Favorable Activity); 1 = Restricted activity but ambulatory; 2 = Ambulatory but unable to carry out work activities; 3 = Limited Self-Care; 4 = Completely Disabled, No self-care (Least Favorable Activity)			
Units: Subjects			
0 - Fully active	1	2	3
1 - Restricted but ambulatory	2	5	11
Missing	0	1	0

Reporting group values	Phase 1: Veliparib 240 mg BID 21 Days + Carboplatin/Etoposide	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo
Number of subjects	4	61	59
Age categorical Units: Subjects			

Age continuous Units: years			
median	59.0	62.0	64.0
full range (min-max)	57.0 to 62.0	39.0 to 77.0	46.0 to 86.0
Gender categorical Units: Subjects			
Female	1	21	21
Male	3	40	38
Race Units: Subjects			
White	4	55	51
Black or African American	0	2	1
Asian	0	4	7
Missing	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status			
Measure Description: ECOG performance status is used by doctors and researchers to assess how a participant's disease is progressing, assess how the disease affects the daily living activities of the participant and determine appropriate treatment and prognosis. 0 = Fully Active (Most Favorable Activity); 1 = Restricted activity but ambulatory; 2 = Ambulatory but unable to carry out work activities; 3 = Limited Self-Care; 4 = Completely Disabled, No self-care (Least Favorable Activity)			
Units: Subjects			
0 - Fully active	2	21	16
1 - Restricted but ambulatory	1	39	42
Missing	1	1	1

Reporting group values	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo	Total	
Number of subjects	61	221	
Age categorical Units: Subjects			

Age continuous Units: years			
median	63.0		
full range (min-max)	37.0 to 87.0	-	
Gender categorical Units: Subjects			
Female	23	79	
Male	38	142	
Race Units: Subjects			
White	52	198	
Black or African American	1	4	
Asian	7	18	
Missing	1	1	
Eastern Cooperative Oncology Group (ECOG) Performance Status			
Measure Description: ECOG performance status is used by doctors and researchers to assess how a participant's disease is progressing, assess how the disease affects the daily living activities of the participant and determine appropriate treatment and prognosis.			

0 = Fully Active (Most Favorable Activity); 1 = Restricted activity but ambulatory; 2 = Ambulatory but unable to carry out work activities; 3 = Limited Self-Care; 4 = Completely Disabled, No self-care (Least Favorable Activity)			
Units: Subjects			
0 - Fully active	23	71	
1 - Restricted but ambulatory	37	145	
Missing	1	5	

End points reporting groups

Reporting group title	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 80 mg veliparib orally twice a day (BID) on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered intravenously (IV) on Day 1 at a target area under the curve (AUC) 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 120 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 160 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 200 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 240 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 240 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 240 mg veliparib orally BID on Days -2 to 12 (14 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 12 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 240 mg BID 21 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 240 mg veliparib orally BID on Days -2 to Day 19 (continuous schedule) in combination with carboplatin/etoposide for up to four 21-day cycles. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib

Reporting group description:

Participants in Arm A received veliparib 240 mg BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min administered on Day 1, and etoposide 100 mg/m² administered on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo

Reporting group description:

Participants In Arm B received veliparib 240 mg BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min administered on Day 1, and etoposide 100 mg/m² administered on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression received placebo monotherapy BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo

Reporting group description:

Participants in Arm C received placebo BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min on Day 1, and etoposide 100 mg/m² on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression received placebo monotherapy BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Subject analysis set title	Phase 1: Veliparib 240 mg BID + Carboplatin/Etoposide Combined
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 240 mg veliparib orally BID (Days -2 to 5 for 7-day schedule, Days -2 to 12 for 14-day schedule or Days -2 to 19 for continuous dosing) in combination with carboplatin/etoposide for up to four 21-day cycles. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.

Subject analysis set title	Etoposide Cycle 1 Day 1 (With Veliparib)
Subject analysis set type	Full analysis

Subject analysis set description:

Phase 1 participants received 100 mg/m² etoposide intravenously with carboplatin target AUC 5.0 mg*min/mL and veliparib 80 to 240 mg BID on Cycle 1 Day 1.

Subject analysis set title	Etoposide Cycle 2 Day 1 (No Veliparib)
Subject analysis set type	Full analysis

Subject analysis set description:

Phase 1 participants received etoposide 100 mg/m² and carboplatin target AUC 5.0 mg*min/mL on Day 1 of Cycle 2. No veliparib was administered.

Primary: Phase 1: Number of Participants With Dose-limiting Toxicities (DLTs)

End point title	Phase 1: Number of Participants With Dose-limiting Toxicities (DLTs)[1][2]

End point description:

A DLT was defined as any of the following drug-related toxicities, graded according to the Common Toxicity Criteria for Adverse Events (CTCAE), V.4.0:
1. Events associated with treatment delay >14 days in initiating Cycle 2 therapy:
Grade 4 thrombocytopenia, neutropenia, or febrile neutropenia, or Grade 3 febrile neutropenia with fever for > 7 days
2. Grade ≥ 3 non-hematologic toxicity with ≥ 2 grade increase from baseline and attributed to veliparib treatment, excluding nausea or vomiting for ≤ 48 hours or inadequately treated, electrolyte abnormalities resolving in ≤ 24 hours, hypersensitivity reactions or alopecia
3. Grade 2 non-hematologic toxicity of ≥ 2 grade increase from baseline, attributed to veliparib treatment requiring delay of >14 days in initiation of Cycle 2
4. Any toxicity of ≥ 2-grade increase from baseline, attributed to veliparib and requiring a dose

modification in Cycle 1 or omission of carboplatin, >1 daily etoposide dose, or >30% veliparib doses in Cycle 1

End point type	Primary

End point timeframe:

Cycle 1 Day –2 to pre-dose on Cycle 2 Day 1 (23 days)

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: Safety results were analyzed 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 pertains to Phase 1 only.

End point values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: participants	0	0	0	0

End point values	Phase 1: Veliparib 240 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 21 Days + Carboplatin/Etoposide	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	4	
Units: participants	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Maximum Observed Plasma Concentration (Cmax) of Veliparib

End point title	Phase 1: Maximum Observed Plasma Concentration (Cmax) of Veliparib[3][4]

End point description:

Plasma concentrations of veliparib were determined using a validated online solid-phase extraction followed by high-performance liquid chromatography with tandem mass spectrometric detection (HPLC LC-MS/MS). The lower limit of quantitation (LLOQ) for veliparib was established at ≥ 1.05 ng/mL.
The number of participants analyzed includes participants who were administered at least 1 dose of study drug, had at least 1 reported PK sample concentration and for whom Cmax could be calculated.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 predose and at 1, 2, 3, 5, 8, and 24 hours post-dose

Notes:

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

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 1 only.

End point values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: µg/mL				
geometric mean (geometric coefficient of variation)	0.620 (± 17)	1.00 (± 31)	1.39 (± 29)	1.44 (± 10)

End point values	Phase 1: Veliparib 240 mg BID + Carboplatin/Etoposide Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: µg/mL				
geometric mean (geometric coefficient of variation)	1.99 (± 25)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Time to Maximum Observed Plasma Concentration (Tmax) of Veliparib

End point title	Phase 1: Time to Maximum Observed Plasma Concentration (Tmax) of Veliparib[5][6]

End point description:

Plasma concentrations of veliparib were determined using a validated online solid-phase extraction followed by high-performance liquid chromatography with tandem mass spectrometric detection (HPLC LC-MS/MS). The lower limit of quantitation (LLOQ) for veliparib was established at ≥ 1.05 ng/mL.
The number of participants analyzed includes participants who were administered at least 1 dose of study drug, had at least 1 reported PK sample concentration and for whom Tmax could be calculated.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 predose and at 1, 2, 3, 5, 8, and 24 hours post-dose

Notes:

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

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 1 only.

End point values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: hours				
median (full range (min-max))	2.0 (1.0 to 2.0)	1.0 (1.0 to 2.0)	1.5 (1.0 to 2.0)	2.0 (1.0 to 2.0)

End point values	Phase 1: Veliparib 240 mg BID + Carboplatin/Etoposide Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: hours				
median (full range (min-max))	1.0 (1.0 to 3.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Area Under the Plasma Concentration-time Curve From Time 0 to 8 Hours Post-dose (AUC[0-8]) of Veliparib

End point title	Phase 1: Area Under the Plasma Concentration-time Curve From Time 0 to 8 Hours Post-dose (AUC[0-8]) of Veliparib[7][8]

End point description:

The area under the plasma concentration-time curve from time 0 to 8 hours post-dose for veliparib was estimated using non-compartmental methods.
The number of participants analyzed includes participants who were administered at least 1 dose of study drug, had at least 1 reported PK sample concentration and for whom AUC(0-8) could be calculated.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 predose and at 1, 2, 3, 5, 8, and 24 hours post-dose

Notes:

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

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 1 only.

End point values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	2
Units: µg*h/mL				
geometric mean (geometric coefficient of variation)	3.18 (± 14)	4.24 (± 25)	7.51 (± 28)	6.66 (± 4)

End point values	Phase 1: Veliparib 240 mg BID + Carboplatin/Etoposide Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: µg*h/mL				
geometric mean (geometric coefficient of variation)	9.29 (± 37)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Area Under the Plasma Concentration-time Curve From Time 0 to 12 Hours Post-dose (AUC[0-12]) of Veliparib

End point title	Phase 1: Area Under the Plasma Concentration-time Curve From Time 0 to 12 Hours Post-dose (AUC[0-12]) of Veliparib[9][10]

End point description:

The area under the plasma concentration-time curve from time 0 to 12 hours post-dose for veliparib was estimated
using non-compartmental methods. AUC(0-12) was calculated by assuming the concentration at 12 hours post-dose
was the same as the pre-dose concentration.
The number of participants analyzed includes participants who were administered at least 1 dose of study drug, had at least 1 reported PK sample concentration and for whom AUC(0-12) could be calculated.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 predose and at 1, 2, 3, 5, 8, and 24 hours post-dose

Notes:

[9] - 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: Pharmacokinetics were analyzed descriptively.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 1 only.

End point values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: µg*h/mL				
geometric mean (geometric coefficient of variation)	4.07 (± 15)	5.25 (± 27)	9.71 (± 31)	8.35 (± 6)

End point values	Phase 1: Veliparib 240 mg BID + Carboplatin/Etoposide Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: µg*h/mL				
geometric mean (geometric coefficient of variation)	11.6 (± 40)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Dose-normalized Maximum Observed Plasma Concentration of Veliparib

End point title	Phase 1: Dose-normalized Maximum Observed Plasma Concentration of Veliparib[11][12]

End point description:

Plasma concentrations of veliparib were determined using a validated online solid-phase extraction followed by high-performance liquid chromatography with tandem mass spectrometric detection (HPLC LC-MS/MS). The lower limit of quantitation (LLOQ) for veliparib was established at ≥ 1.05 ng/mL.
Dose normalized Cmax is calculated as Cmax / veliparib dose in mg.
The number of participants analyzed includes participants who were administered at least 1 dose of study drug, had at least 1 reported PK sample concentration and for whom Cmax could be calculated.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 predose and at 1, 2, 3, 5, 8, and 24 hours post-dose

Notes:

[11] - 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: Pharmacokinetics were analyzed descriptively.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 1 only.

End point values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: (ng/mL)/mg				
geometric mean (geometric coefficient of variation)	7.75 (± 16)	8.35 (± 31)	8.66 (± 29)	7.19 (± 10)

End point values	Phase 1: Veliparib 240 mg BID + Carboplatin/Etoposide Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: (ng/mL)/mg				
geometric mean (geometric coefficient of variation)	8.31 (± 25)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Dose-normalized Area Under the Plasma Concentration-time Curve From Time 0 to 8 Hours Post-dose of Veliparib

End point title	Phase 1: Dose-normalized Area Under the Plasma Concentration-time Curve From Time 0 to 8 Hours Post-dose of Veliparib[13][14]

End point description:

The area under the plasma concentration-time curve from time 0 to 8 hours post-dose for veliparib was estimated using non-compartmental methods.
Dose normalized AUC(0-8) is calculated as AUC(0-8) / veliparib dose in mg.
The number of participants analyzed includes participants who were administered at least 1 dose of study drug, had at least 1 reported PK sample concentration and for whom AUC(0-8) could be calculated.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 predose and at 1, 2, 3, 5, 8, and 24 hours post-dose

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Pharmacokinetics were analyzed descriptively.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 1 only.

End point values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	2
Units: (ng*h/mL)/mg				
geometric mean (geometric coefficient of variation)	39.8 (± 14)	35.3 (± 25)	46.9 (± 28)	33.3 (± 4)

End point values	Phase 1: Veliparib 240 mg BID + Carboplatin/Etoposide Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: (ng*h/mL)/mg				
geometric mean (geometric coefficient of variation)	38.7 (± 37)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Dose-normalized Area Under the Plasma Concentration-time Curve From Time 0 to 12 Hours Post-dose of Veliparib

End point title	Phase 1: Dose-normalized Area Under the Plasma Concentration-time Curve From Time 0 to 12 Hours Post-dose of Veliparib[15][16]

End point description:

The area under the plasma concentration-time curve from time 0 to 12 hours post-dose for veliparib was estimated using non-compartmental methods. AUC(0-12) was calculated by assuming the concentration at 12 hours post-dose was the same as the pre-dose concentration. Dose normalized AUC(0-12) is calculated as AUC(0-12) / veliparib dose in mg.
The number of participants analyzed includes participants who were administered at least 1 dose of study drug, had at least 1 reported PK sample concentration and for whom AUC(0-12) could be calculated.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 predose and at 1, 2, 3, 5, 8, and 24 hours post-dose

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Pharmacokinetics were analyzed descriptively.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 1 only.

End point values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: (ng*h/mL)/mg				
geometric mean (geometric coefficient of variation)	50.9 (± 15)	43.8 (± 27)	60.7 (± 31)	41.7 (± 6)

End point values	Phase 1: Veliparib 240 mg BID + Carboplatin/Etoposide Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: (ng*h/mL)/mg				
geometric mean (geometric coefficient of variation)	48.5 (± 40)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Maximum Observed Plasma Concentration (Cmax) of Etoposide With and Without Veliparib

End point title	Phase 1: Maximum Observed Plasma Concentration (Cmax) of Etoposide With and Without Veliparib[17]

End point description:

Etoposide plasma concentrations were determined using liquid chromatography with tandem mass spectrometric detection with a lower limit of quantitation 160 ng/mL.
The number of participants analyzed includes participants who received at least 1 dose of study drug, had at least 1 reported PK sample concentration for each time point and for whom Cmax could be calculated. Participants in the Veliparib 240 mg BID 21-day (continuous) dosing group and participants whose etoposide dose was reduced in Cycle 2 are not included in the Cycle 2 Day 1 analysis.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 (coadministered with veliparib and carboplatin), and on Cycle 2 Day 1 (co-administered with carboplatin but in the absence of veliparib) at 55 minutes (5 minutes before the end of infusion) and 3, 5, 8, and 24 hours post-dose.

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Pharmacokinetics were analyzed descriptively.

End point values	Etoposide Cycle 1 Day 1 (With Veliparib)	Etoposide Cycle 2 Day 1 (No Veliparib)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	37	23		
Units: µg/mL				
geometric mean (geometric coefficient of variation)	16.9 (± 18)	16.4 (± 21)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Time to Maximum Observed Plasma Concentration (Tmax) of Etoposide With and Without Veliparib

End point title	Phase 1: Time to Maximum Observed Plasma Concentration (Tmax) of Etoposide With and Without Veliparib[18]

End point description:

Etoposide plasma concentrations were determined using liquid chromatography with tandem mass spectrometric detection with a lower limit of quantitation 160 ng/mL.
The number of participants analyzed includes participants who received at least 1 dose of study drug, had at least 1 reported PK sample concentration for each time point and for whom Tmax could be calculated. Participants in the Veliparib 240 mg BID 21-day (continuous) dosing group are not included in the Cycle 2 Day 1 analysis.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 (coadministered with veliparib and carboplatin), and on Cycle 2 Day 1 (co-administered with carboplatin but in the absence of veliparib) at 55 minutes (5 minutes before the end of infusion) and 3, 5, 8, and 24 hours post-dose.

Notes:

[18] - 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: Pharmacokinetics were analyzed descriptively.

End point values	Etoposide Cycle 1 Day 1 (With Veliparib)	Etoposide Cycle 2 Day 1 (No Veliparib)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	37	28		
Units: hours				
median (full range (min-max))	0.9 (0.8 to 3.0)	0.9 (0.9 to 3.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Area Under the Concentration-time Curve From Time 0 to Time of Last Measurable Concentration (AUC[0-t]) of Etoposide With and Without Veliparib

End point title	Phase 1: Area Under the Concentration-time Curve From Time 0 to Time of Last Measurable Concentration (AUC[0-t]) of

	Etoposide With and Without Veliparib[19]

End point description:

The area under the plasma concentration-time curve from 0 to the last measurable concentration (24 hours) of
etoposide was estimated using using non-compartmental methods.
The number of participants analyzed includes participants who received at least 1 dose of study drug, had at least 1 reported PK sample concentration for each time point and for whom AUC(0-t) could be calculated. Participants in the Veliparib 240 mg BID 21-day (continuous) dosing group and participants whose etoposide dose was reduced in Cycle 2 are not included in the Cycle 2 Day 1 analysis.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 (coadministered with veliparib and carboplatin), and on Cycle 2 Day 1 (co-administered with carboplatin but in the absence of veliparib) at 55 minutes (5 minutes before the end of infusion) and 3, 5, 8, and 24 hours post-dose.

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Pharmacokinetics were analyzed descriptively.

End point values	Etoposide Cycle 1 Day 1 (With Veliparib)	Etoposide Cycle 2 Day 1 (No Veliparib)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	22		
Units: µg*h/mL				
geometric mean (geometric coefficient of variation)	102 (± 23)	94.7 (± 18)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Area Under the Concentration-time Curve From Time 0 to Infinity (AUC[0-∞]) of Etoposide With and Without Veliparib

End point title	Phase 1: Area Under the Concentration-time Curve From Time 0 to Infinity (AUC[0-∞]) of Etoposide With and Without Veliparib[20]

End point description:

The area under the plasma concentration-time curve from 0 to infinity for etoposide was estimated using using non-compartmental methods.
The number of participants analyzed includes participants who received at least 1 dose of study drug, had at least 1 reported PK sample concentration for each time point and for whom AUC(0-∞) could be calculated. Participants in the Veliparib 240 mg BID 21-day (continuous) dosing group and participants whose etoposide dose was reduced in Cycle 2 are not included in the Cycle 2 Day 1 analysis.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 (coadministered with veliparib and carboplatin), and on Cycle 2 Day 1 (co-administered with carboplatin but in the absence of veliparib) at 55 minutes (5 minutes before the end of infusion) and 3, 5, 8, and 24 hours post-dose.

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: Pharmacokinetics were analyzed descriptively.

End point values	Etoposide Cycle 1 Day 1 (With Veliparib)	Etoposide Cycle 2 Day 1 (No Veliparib)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	22		
Units: µg*h/m				
geometric mean (geometric coefficient of variation)	112 (± 56)	99.5 (± 18)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Terminal Phase Elimination Half-life (t1/2) of Etoposide With and Without Veliparib

End point title	Phase 1: Terminal Phase Elimination Half-life (t1/2) of Etoposide With and Without Veliparib[21]

End point description:

The terminal half-life of etoposide was estimated using using non-compartmental methods. Values reported represent the harmonic mean ± pseudo-standard deviation.
The number of participants analyzed includes participants who received at least 1 dose of study drug, had at least 1 reported PK sample concentration for each time point and for whom t1/2 could be calculated. Participants in the Veliparib 240 mg BID 21-day (continuous) dosing group are not included in the Cycle 2 Day 1 analysis.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 (coadministered with veliparib and carboplatin), and on Cycle 2 Day 1 (co-administered with carboplatin but in the absence of veliparib) at 55 minutes (5 minutes before the end of infusion) and 3, 5, 8, and 24 hours post-dose.

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Pharmacokinetics were analyzed descriptively.

End point values	Etoposide Cycle 1 Day 1 (With Veliparib)	Etoposide Cycle 2 Day 1 (No Veliparib)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	27		
Units: hours				
arithmetic mean (standard deviation)	5.7 (± 1.5)	5.0 (± 1.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Dose-normalized Maximum Observed Plasma Concentration (Cmax) of Etoposide With and Without Veliparib

End point title	Phase 1: Dose-normalized Maximum Observed Plasma Concentration (Cmax) of Etoposide With and Without Veliparib

	[22]

End point description:

Etoposide plasma concentrations were determined using liquid chromatography with tandem mass spectrometric detection with a lower limit of quantitation 160 ng/mL. Dose normalized Cmax is calculated as Cmax / etoposide dose in mg/m².
The number of participants analyzed includes participants who received at least 1 dose of study drug, had at least 1 reported PK sample concentration for each time point and for whom Cmax could be calculated. Participants in the Veliparib 240 mg BID 21-day (continuous) dosing group are not included in the Cycle 2 Day 1 analysis.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 (coadministered with veliparib and carboplatin), and on Cycle 2 Day 1 (co-administered with carboplatin but in the absence of veliparib) at 55 minutes (5 minutes before the end of infusion) and 3, 5, 8, and 24 hours post-dose.

Notes:

[22] - 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: Pharmacokinetics were analyzed descriptively.

End point values	Etoposide Cycle 1 Day 1 (With Veliparib)	Etoposide Cycle 2 Day 1 (No Veliparib)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	37	28		
Units: (ng/mL)/(mg/m²)				
geometric mean (geometric coefficient of variation)	169 (± 18)	170 (± 20)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Dose-normalized Area Under the Concentration-time Curve From Time 0 to Time of Last Measurable Concentration (AUC[0-t]) of Etoposide With and Without Veliparib

End point title	Phase 1: Dose-normalized Area Under the Concentration-time Curve From Time 0 to Time of Last Measurable Concentration (AUC[0-t]) of Etoposide With and Without Veliparib[23]

End point description:

The area under the plasma concentration-time curve from 0 to the last measurable concentration (24 hours) of
etoposide was estimated using using non-compartmental methods. Dose normalized AUC(0-t) is calculated as AUC(0-t) / etoposide dose in mg/m².
The number of participants analyzed includes participants who received at least 1 dose of study drug, had at least 1 reported PK sample concentration for each time point and for whom AUC(0-t) could be calculated. Participants in the Veliparib 240 mg BID 21-day (continuous) dosing group are not included in the Cycle 2 Day 1 analysis.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 (coadministered with veliparib and carboplatin), and on Cycle 2 Day 1 (co-administered with carboplatin but in the absence of veliparib) at 55 minutes (5 minutes before the end of infusion) and 3, 5, 8, and 24 hours post-dose.

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Pharmacokinetics were analyzed descriptively.

End point values	Etoposide Cycle 1 Day 1 (With Veliparib)	Etoposide Cycle 2 Day 1 (No Veliparib)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	27		
Units: (ng*h/mL)/(mg/m²)				
geometric mean (geometric coefficient of variation)	1020 (± 23)	952 (± 21)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Dose-normalized Area Under the Concentration-time Curve From Time 0 to Infinity (AUC[0-∞]) of Etoposide With and Without Veliparib

End point title	Phase 1: Dose-normalized Area Under the Concentration-time Curve From Time 0 to Infinity (AUC[0-∞]) of Etoposide With and Without Veliparib[24]

End point description:

The area under the plasma concentration-time curve from 0 to infinity for etoposide was estimated using using non-compartmental methods. Dose normalized AUC(0-∞) is calculated as AUC(0-∞) / etoposide dose in mg/m².
The number of participants analyzed includes participants who received at least 1 dose of study drug, had at least 1 reported PK sample concentration for each time point and for whom AUC(0-∞) could be calculated. Participants in the Veliparib 240 mg BID 21-day (continuous) dosing group are not included in the Cycle 2 Day 1 analysis.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 (coadministered with veliparib and carboplatin), and on Cycle 2 Day 1 (co-administered with carboplatin but in the absence of veliparib) at 55 minutes (5 minutes before the end of infusion) and 3, 5, 8, and 24 hours post-dose.

Notes:

[24] - 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: Pharmacokinetics were analyzed descriptively.

End point values	Etoposide Cycle 1 Day 1 (With Veliparib)	Etoposide Cycle 2 Day 1 (No Veliparib)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	27		
Units: ng*h/mL)/(mg/m²)				
geometric mean (geometric coefficient of variation)	1120 (± 56)	1020 (± 20)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Progression-free Survival

End point title	Phase 2: Progression-free Survival[25]

End point description:

Progression-free survival (PFS) is defined as the time from the date of randomization to the date of earliest radiographic disease progression or death if no radiographic disease progression occurred.
If a participant did not have an event of disease progression and had not died on or prior to the cutoff for PFS analysis, the participant was censored at the date of their last disease assessment or randomization date provided they did not have any post-baseline disease assessment.
Disease assessments were performed using computed tomography according to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1.
Progressive Disease (PD) was defined as at least a 20% increase in the size of target lesions and an absolute increase of at least 5 mm taking as reference the smallest lesion size recorded since the treatment started (baseline or after), or the appearance of 1 or more new lesions.
The number of participants analyzed includes all participants randomized in Phase 2.

End point type	Primary

End point timeframe:

From randomization up to the date the 126th PFS event was reached; Median time on follow-up was 7.3, 7.1, and 8.9 months in each treatment group respectively.

Notes:

[25] - 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 pertains to Phase 2 only.

End point values	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	59	61	
Units: months				
median (confidence interval 80%)	5.8 (5.6 to 6.8)	5.7 (5.6 to 5.8)	5.6 (5.1 to 6.7)	

Statistical analyses

Statistical analysis title	Primary Analysis of PFS (Arm A vs. Arm C)

Statistical analysis description:

The primary efficacy analysis in the Phase 2 portion of the study was the comparison of PFS among participants who received veliparib in combination with carboplatin and etoposide followed by veliparib maintenance monotherapy (Arm A) vs. placebo in combination with carboplatin and etoposide followed by placebo maintenance monotherapy (Arm C).
The hazard ratio was estimated from a Cox proportional hazards model stratified by lactate dehydrogenase (LDH) level. A hazard ratio < 1 favors Arm A.

Comparison groups	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib v Phase 2: Placebo + Carboplatin/Etoposide -> Placebo
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[26]
P-value	= 0.059 [27]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.665

Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.503
upper limit	0.88

Notes:

[26] - Statistical significance was determined by a two-sided p-value ≤ 0.2.

[27] - Two-sided log-rank test stratified by lactate dehydrogenase (LDH) level.

Statistical analysis title	Secondary Analysis of PFS (Arm B vs. Arm C)

Statistical analysis description:

The analysis of PFS between Arm B versus Arm C was considered a secondary endpoint in the testing hierarchy (see details below), and was compared using a two-sided log-rank test stratified by LDH level. The hazard ratio was estimated from a Cox proportional hazards model stratified by LDH level. A hazard ratio of < 1 favors Arm B.

Comparison groups	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo v Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority[28]
P-value	= 0.924 [29]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.979
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.744
upper limit	1.288

Notes:

[28] - If the primary analysis of PFS (Arm A vs Arm C) was statistically significant a fixed sequence testing procedure was to be performed with a 2-sided significance level of 0.2 for the following key secondary endpoints:
OS (Arm A vs Arm C)
PFS (Arms B vs Arm C)
OS (Arm B vs Arm C)
ORR (Arm A vs Arm C)
ORR (Arm B vs Arm C)
If significance versus Arm C was not demonstrated, all endpoints later in the testing hierarchy were to be considered exploratory.

[29] - Two-sided log-rank test stratified by lactate dehydrogenase (LDH) level.

Secondary: Phase 2: Overall Survival

End point title	Phase 2: Overall Survival[30]

End point description:

Overall survival (OS) is defined as the time from the date of randomization to the date of death. If a participant did not die on or prior to the end of study, the participant was censored at the date of their last known alive date, which is defined as the last date of the last survival follow-up visit, the start date of the last adverse event (AE), the start date or end date of the last dose of any study drugs, the last lab and vital sign collection date, or the last disease assessment date, whichever occurred last.
The number of participants analyzed includes all participants randomized in Phase 2.

End point type	Secondary

End point timeframe:

From randomization until the end of study (after a total of 136 OS events); median time on follow-up was 10.0, 8.6, and 11.7 months in each treatment group respectively.

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 2 only.

End point values	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	59	61	
Units: months				
median (confidence interval 80%)	10.1 (9.2 to 11.4)	10.0 (8.0 to 12.7)	12.4 (11.1 to 13.6)	

Statistical analyses

Statistical analysis title	Overall Survival of Arm A vs. Arm C

Statistical analysis description:

The analysis of OS between Arm A versus Arm C was a key secondary endpoint in the testing hierarchy (see details below), and was compared using a two-sided log-rank test stratified by LDH level.
The hazard ratio was estimated from a Cox proportional hazards model stratified by LDH level. A hazard ratio of < 1 favors Arm A.

Comparison groups	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib v Phase 2: Placebo + Carboplatin/Etoposide -> Placebo
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[31]
P-value	= 0.088 [32]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.432
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	1.092
upper limit	1.879

Notes:

[31] - If the primary analysis of PFS (Arm A vs Arm C) was statistically significant a fixed sequence testing procedure was to be performed with a 2-sided significance level of 0.2 for the following key secondary endpoints:
OS (Arm A vs Arm C)
PFS (Arms B vs Arm C)
OS (Arm B vs Arm C)
ORR (Arm A vs Arm C)
ORR (Arm B vs Arm C)
If significance versus Arm C was not demonstrated, all endpoints later in the testing hierarchy were to be considered exploratory.
[32] - Two-sided log rank test stratified by LDH level.

Statistical analysis title	Overall Survival of Arm B vs. Arm C

Statistical analysis description:

The analysis of OS between Arm B versus Arm C was a key secondary endpoint in the testing hierarchy (see details below), and was compared using a two-sided log-rank test stratified by LDH level.

The hazard ratio was estimated from a Cox proportional hazards model stratified by LDH level. A hazard ratio of < 1 favors Arm B.

Comparison groups	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo v Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority[33]
P-value	= 0.083 [34]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.46
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	1.104
upper limit	1.931

Notes:

[33] - If the primary analysis of PFS (Arm A vs Arm C) was statistically significant a fixed sequence testing procedure was to be performed with a 2-sided significance level of 0.2 for the following key secondary endpoints:
OS (Arm A vs Arm C)
PFS (Arms B vs Arm C)
OS (Arm B vs Arm C)
ORR (Arm A vs Arm C)
ORR (Arm B vs Arm C)
If significance versus Arm C was not demonstrated, all endpoints later in the testing hierarchy were to be considered exploratory.

[34] - Two-sided log rank test stratified by LDH level.

Secondary: Phase 2: Objective Response Rate

End point title	Phase 2: Objective Response Rate[35]

End point description:

Objective response rate (ORR) is defined as the percentage of participants with objective response (confirmed) as assessed by the investigator using RECIST version 1.1. Objective response includes both complete response (CR) and partial response (PR). Response must be confirmed at a subsequent tumor assessment at least 28 days apart. Participants with no post-baseline confirmed response were counted as non-responders.
CR: Disappearance of all target and non-target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm. No new lesions.
PR: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters, and no new lesions.
The number of participants analyzed includes all participants randomized in Phase 2.

End point type	Secondary

End point timeframe:

Tumor assessments were performed every 6 weeks for the first 30 weeks and every 9 weeks thereafter until disease progression; median time on follow-up was 7.3, 7.1, and 8.9 months in each group respectively.

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 2 only.

End point values	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	59	61	
Units: percentage of participants				
number (confidence interval 80%)	77.0 (68.7 to 84.0)	59.3 (50.1 to 68.0)	63.9 (55.0 to 72.2)	

Statistical analyses

Statistical analysis title	Objective Response Rate of Arm A vs Arm C

Statistical analysis description:

The analysis of ORR between Arm A versus Arm C was a key secondary endpoint in the testing hierarchy (see details below), and was compared using a two-sided Cochran-Mantel-Haenszel test stratified by LDH level.
An odds ratio of > 1 favors Arm A.

Comparison groups	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib v Phase 2: Placebo + Carboplatin/Etoposide -> Placebo
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[36]
P-value	= 0.115 [37]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.9
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	1.1
upper limit	3.2

Notes:

[36] - If the primary analysis of PFS (Arm A vs Arm C) was statistically significant a fixed sequence testing procedure was to be performed with a 2-sided significance level of 0.2 for the following key secondary endpoints:
OS (Arm A vs Arm C)
PFS (Arms B vs Arm C)
OS (Arm B vs Arm C)
ORR (Arm A vs Arm C)
ORR (Arm B vs Arm C)
If significance versus Arm C was not demonstrated, all endpoints later in the testing hierarchy were to be considered exploratory.

[37] - Cochran-Mantel-Haenszel test stratified by LDH level.

Statistical analysis title	Objective Response Rate of Arm B vs Arm C

Statistical analysis description:

The analysis of ORR between Arm B versus Arm C was a key secondary endpoint in the testing hierarchy (see details below), and was compared using a two-sided Cochran-Mantel-Haenszel test stratified by LDH level.
An odds ratio of > 1 favors Arm B.

Comparison groups	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo v Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority[38]
P-value	= 0.604 [39]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.5
upper limit	1.3

Notes:

[38] - If the primary analysis of PFS (Arm A vs Arm C) was statistically significant a fixed sequence testing procedure was to be performed with a 2-sided significance level of 0.2 for the following key secondary endpoints:
OS (Arm A vs Arm C)
PFS (Arms B vs Arm C)
OS (Arm B vs Arm C)
ORR (Arm A vs Arm C)
ORR (Arm B vs Arm C)
If significance versus Arm C was not demonstrated, all endpoints later in the testing hierarchy were to be considered exploratory.
[39] - Cochran-Mantel-Haenszel test stratified by LDH level.

Secondary: Phase 1: Number of Participants With Adverse Events

End point title	Phase 1: Number of Participants With Adverse Events[40]

End point description:

The intensity of each adverse event (AE) was assessed utilizing the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 4.0, and according to the following: Grade 1 (Mild): AE is transient and easily tolerated by the participant; Grade 2 (Moderate): AE causes the participant discomfort and interrupts the participant's usual activities; Grade 3/4 (Severe): The adverse event causes considerable interference with the participant's usual activities and may be incapacitating or life-threatening; Grade 5: Death.
Serious adverse events were those that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization, resulted in congenital anomaly, or persistent or significant disability/incapacity.
The number of participants analyzed includes all participants enrolled in the Phase 1 portion of the study who received at least 1 dose of study treatment.

End point type	Secondary

End point timeframe:

From first dose of any study drug to 30 days after the last dose; the median duration of treatment with veliparib across all groups in Phase 1 was 127.5 days.

Notes:

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint pertains to Phase 1 only.

End point values	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: participants				
Any adverse event	4	3	4	3

Any AE Grade 3/4	4	3	4	3
Any serious adverse event	3	1	3	2
Any fatal adverse event	0	0	1	1

End point values	Phase 1: Veliparib 240 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 21 Days + Carboplatin/Etoposide	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	14	4	
Units: participants				
Any adverse event	8	14	4	
Any AE Grade 3/4	7	14	4	
Any serious adverse event	3	6	3	
Any fatal adverse event	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Deaths are reported from enrollment to end of study, maximum time on follow-up was 26 months. AEs were collected from first dose of study drug until 30 days after last dose; Maximum duration of treatment was 541 days in Phase 1 and 654 days in Phase 2.

Adverse event reporting additional description:

Adverse events and deaths are reported for all participants who received at least 1 dose of study drug (safety population). One participant randomized in Phase 2 to Arm A died before receiving treatment and was not included in the safety population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 80 mg veliparib orally twice a day (BID) on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered intravenously (IV) on Day 1 at a target area under the curve (AUC) 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 120 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 160 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 200 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 240 mg BID 7 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 240 mg veliparib orally BID on Days -2 to 5 (7 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 5 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.

Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 240 mg BID 21 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 240 mg veliparib orally BID on Days -2 to Day 19 (continuous schedule) in combination with carboplatin/etoposide for up to four 21-day cycles. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide

Reporting group description:

Participants received 240 mg veliparib orally BID on Days -2 to 12 (14 days) in combination with carboplatin/etoposide for up to four 21-day cycles, with the exception of Cycle 2, when veliparib was administered on Days 2 to 12 to allow for evaluation of potential impact of veliparib on etoposide pharmacokinetics. Carboplatin was administered IV on Day 1 at a target AUC 5 mg/mL*minute and etoposide 100 mg/m² IV on Days 1 to 3 of every 21-day cycle.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo

Reporting group description:

Participants in Arm B received veliparib 240 mg BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min administered on Day 1, and etoposide 100 mg/m² administered on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression received placebo monotherapy BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib

Reporting group description:

Participants in Arm A received veliparib 240 mg BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min administered on Day 1, and etoposide 100 mg/m² administered on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression continued on veliparib monotherapy at 400 mg BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Reporting group title	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo

Reporting group description:

Participants in Arm C received placebo BID on Day -2 to 12 (14-day schedule), carboplatin AUC 5 mg/mL*min on Day 1, and etoposide 100 mg/m² on Days 1 to 3 of each 21-day cycle for up to 6 cycles.
Participants without evidence of disease progression received placebo monotherapy BID continuous dosing (21-day cycles) until disease progression or unacceptable toxicity.

Serious adverse events	Phase 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	1 / 3 (33.33%)	3 / 4 (75.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 CENTRAL NERVOUS SYSTEM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
AORTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
PERIPHERAL ARTERY THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
PERIPHERAL EMBOLISM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
SUPERIOR VENA CAVA SYNDROME			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 1
VENA CAVA THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 / 1
FATIGUE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
MALAISE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
PYREXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
SUDDEN CARDIAC DEATH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
SUDDEN DEATH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
ACUTE RESPIRATORY FAILURE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
ATELECTASIS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (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
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
HAEMOPTYSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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	1 / 4 (25.00%)	0 / 3 (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
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 EMBOLISM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
DEPRESSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	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
Injury, poisoning and procedural complications			
VASCULAR PROCEDURE COMPLICATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
SINUS NODE DYSFUNCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			

CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
DIZZINESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
MIGRAINE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
MOTOR DYSFUNCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
TOXIC NEUROPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (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
LEUKOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
PANCYTOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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	1 / 4 (25.00%)	0 / 3 (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
DUODENAL ULCER PERFORATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
DYSPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 1
GASTRIC PERFORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
GASTRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
HAEMATEMESIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
ILEUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL ISCHAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
MOUTH HAEMORRHAGE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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	1 / 4 (25.00%)	0 / 3 (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
PALATAL OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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			
HEPATIC FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
Endocrine disorders			
DIABETES INSIPIDUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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	1 / 4 (25.00%)	0 / 3 (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
BACK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
BURSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
FLANK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 SEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
ANAL ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
CELLULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
ENCEPHALITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
IMPLANT SITE CELLULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
ORCHITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
PNEUMONIA INFLUENZAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 LEGIONELLA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
SEPTIC SHOCK			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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			
DECREASED APPETITE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
DEHYDRATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 1: Veliparib 200 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 240 mg BID 21 Days + Carboplatin/Etoposide
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	3 / 8 (37.50%)	3 / 4 (75.00%)
number of deaths (all causes)	1	0	0
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 / 3 (0.00%)	0 / 8 (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	1 / 3 (33.33%)	0 / 8 (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
METASTASES TO CENTRAL NERVOUS SYSTEM			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
AORTITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
PERIPHERAL ARTERY THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
PERIPHERAL EMBOLISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
SUPERIOR VENA CAVA SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
VENA CAVA THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	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
General disorders and administration site conditions			

ASTHENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
MALAISE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	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
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
OEDEMA PERIPHERAL			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
SUDDEN CARDIAC DEATH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
SUDDEN DEATH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
ATELECTASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
CHRONIC OBSTRUCTIVE			

PULMONARY DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
HAEMOPTYSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 EMBOLISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
DEPRESSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
VASCULAR PROCEDURE COMPLICATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
CARDIAC FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
SINUS NODE DYSFUNCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
DIZZINESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
MIGRAINE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
MOTOR DYSFUNCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
TOXIC NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	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
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (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
LEUKOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
NEUTROPENIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
PANCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
COLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 PERFORATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
DYSPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
GASTRIC PERFORATION			

subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (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
GASTRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
HAEMATEMESIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
ILEUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
INTESTINAL ISCHAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
MOUTH HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
PALATAL OEDEMA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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			
HEPATIC FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
Endocrine disorders			
DIABETES INSIPIDUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
BACK PAIN			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
BURSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
FLANK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 SEPSIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (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
ANAL ABSCESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
CELLULITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
ENCEPHALITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
IMPLANT SITE CELLULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
ORCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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 INFLUENZAL			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 LEGIONELLA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
SEPTIC SHOCK			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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			
DECREASED APPETITE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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
DEHYDRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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 / 3 (0.00%)	0 / 8 (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
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (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	1 / 3 (33.33%)	0 / 8 (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

Serious adverse events	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 14 (42.86%)	39 / 58 (67.24%)	33 / 60 (55.00%)
number of deaths (all causes)	0	45	49
number of deaths resulting from adverse events	0	10	7
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (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
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 14 (0.00%)	5 / 58 (8.62%)	5 / 60 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 3
METASTASES TO CENTRAL NERVOUS SYSTEM			
subjects affected / exposed	1 / 14 (7.14%)	4 / 58 (6.90%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

AORTITIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGE			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL ARTERY THROMBOSIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL EMBOLISM			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPERIOR VENA CAVA SYNDROME			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
VENA CAVA THROMBOSIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CHEST PAIN			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
DISEASE PROGRESSION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
MALAISE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
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 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			

subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	1 / 14 (7.14%)	2 / 58 (3.45%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN CARDIAC DEATH			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DYSPNOEA			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPISTAXIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
HAEMOPTYSIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 14 (0.00%)	3 / 58 (5.17%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
PULMONARY HAEMORRHAGE			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
RESPIRATORY FAILURE			

subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
Investigations			
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
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			
VASCULAR PROCEDURE COMPLICATION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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 disorders			
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			

subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
SINUS NODE DYSFUNCTION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
HEADACHE			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
ISCHAEMIC STROKE			

subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MIGRAINE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MOTOR DYSFUNCTION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
TOXIC NEUROPATHY			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 14 (0.00%)	3 / 58 (5.17%)	3 / 60 (5.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 14 (7.14%)	7 / 58 (12.07%)	5 / 60 (8.33%)
occurrences causally related to treatment / all	1 / 1	5 / 7	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOPENIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 14 (0.00%)	4 / 58 (6.90%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 0	1 / 5	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCYTOPENIA			

subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 14 (0.00%)	6 / 58 (10.34%)	3 / 60 (5.00%)
occurrences causally related to treatment / all	0 / 0	3 / 9	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
DUODENAL ULCER PERFORATION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC PERFORATION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			

subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
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 INFLAMMATION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATEMESIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEUS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL ISCHAEMIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MOUTH HAEMORRHAGE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	1 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALATAL OEDEMA			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			

subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
HEPATIC FAILURE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (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
Endocrine disorders			
DIABETES INSIPIDUS			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (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
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BURSITIS			

subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (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
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
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 SEPSIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAL ABSCESS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
BRONCHITIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
ENCEPHALITIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
IMPLANT SITE CELLULITIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTION			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	0 / 60 (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
ORCHITIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL INFECTION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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	0 / 14 (0.00%)	3 / 58 (5.17%)	7 / 60 (11.67%)
occurrences causally related to treatment / all	0 / 0	0 / 3	2 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 2
PNEUMONIA INFLUENZAL			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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 LEGIONELLA			

subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
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 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
SEPTIC SHOCK			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	3 / 60 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (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
HYPOMAGNESAEMIA			

subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	1 / 14 (7.14%)	3 / 58 (5.17%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	27 / 60 (45.00%)		
number of deaths (all causes)	41		
number of deaths resulting from adverse events	5		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	5 / 60 (8.33%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
METASTASES TO CENTRAL NERVOUS SYSTEM			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
AORTITIS			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
HAEMORRHAGE			

subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HYPOTENSION				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
PERIPHERAL ARTERY THROMBOSIS				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
PERIPHERAL EMBOLISM				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SUPERIOR VENA CAVA SYNDROME				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
VENA CAVA THROMBOSIS				
subjects affected / exposed	0 / 60 (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	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
CHEST PAIN				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
DEATH				

subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
DISEASE PROGRESSION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FATIGUE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
GENERAL PHYSICAL HEALTH DETERIORATION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
MALAISE				
subjects affected / exposed	0 / 60 (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 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
OEDEMA PERIPHERAL				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PAIN				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PYREXIA				

subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SUDDEN CARDIAC DEATH				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
SUDDEN DEATH				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
ACUTE RESPIRATORY DISTRESS SYNDROME				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
ACUTE RESPIRATORY FAILURE				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
ATELECTASIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
DYSPNOEA				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

EPISTAXIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HAEMOPTYSIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PLEURAL EFFUSION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA ASPIRATION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMONITIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PULMONARY EMBOLISM				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
PULMONARY HAEMORRHAGE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
RESPIRATORY FAILURE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				

DEPRESSION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
PLATELET COUNT DECREASED				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
TRANSAMINASES INCREASED				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
VASCULAR PROCEDURE COMPLICATION				
subjects affected / exposed	0 / 60 (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 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ATRIAL FIBRILLATION				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
CARDIAC FAILURE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CARDIO-RESPIRATORY ARREST				

subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
MYOCARDIAL INFARCTION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SINUS NODE DYSFUNCTION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VENTRICULAR TACHYCARDIA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
CEREBRAL ISCHAEMIA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
DIZZINESS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HEADACHE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ISCHAEMIC STROKE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
MIGRAINE				

subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
MOTOR DYSFUNCTION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
TOXIC NEUROPATHY				
subjects affected / exposed	0 / 60 (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	2 / 60 (3.33%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
FEBRILE NEUTROPENIA				
subjects affected / exposed	3 / 60 (5.00%)			
occurrences causally related to treatment / all	3 / 3			
deaths causally related to treatment / all	0 / 0			
LEUKOPENIA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
NEUTROPENIA				
subjects affected / exposed	2 / 60 (3.33%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
PANCYTOPENIA				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
THROMBOCYTOPENIA				

subjects affected / exposed	2 / 60 (3.33%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COLITIS			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
DIARRHOEA			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
DUODENAL ULCER PERFORATION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
DYSPHAGIA			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
GASTRIC PERFORATION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
GASTRITIS			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
GASTROINTESTINAL INFLAMMATION			

subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
HAEMATEMESIS				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
ILEUS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
INTESTINAL ISCHAEMIA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
MOUTH HAEMORRHAGE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
NAUSEA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PALATAL OEDEMA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VOMITING				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
HEPATIC FAILURE				

subjects affected / exposed	0 / 60 (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 / 60 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
DIABETES INSIPIDUS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BACK PAIN			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BURSITIS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
FLANK PAIN			

subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
MUSCULOSKELETAL PAIN				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PAIN IN EXTREMITY				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
ABDOMINAL SEPSIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ANAL ABSCESS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
BRONCHITIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CELLULITIS				
subjects affected / exposed	0 / 60 (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 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ENCEPHALITIS				

subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
IMPLANT SITE CELLULITIS				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
INFECTION				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
ORCHITIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PLEURAL INFECTION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA INFLUENZAL				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA LEGIONELLA				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
RESPIRATORY TRACT INFECTION				

subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
SEPSIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SEPTIC SHOCK				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
URINARY TRACT INFECTION				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
DECREASED APPETITE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
DEHYDRATION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HYPOKALAEMIA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HYPOMAGNESAEMIA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HYPONATRAEMIA				

subjects affected / exposed	0 / 60 (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 1: Veliparib 80 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 120 mg BID 7 Days + Carboplatin/Etoposide	Phase 1: Veliparib 160 mg BID 7 Days + Carboplatin/Etoposide
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	3 / 3 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
METASTASES TO CENTRAL NERVOUS SYSTEM			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
HYPERTENSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HYPOTENSION			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
INTERMITTENT CLAUDICATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
CHEST PAIN			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
CREPITATIONS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CRYING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	2 / 4 (50.00%)	3 / 3 (100.00%)	1 / 4 (25.00%)
occurrences (all)	3	5	2
FEELING ABNORMAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FEELING COLD			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
GAIT DISTURBANCE			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	4
INJECTION SITE EXTRAVASATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE HAEMATOMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE PHLEBITIS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
LOSS OF CONTROL OF LEGS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
MALAISE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NECROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
SWELLING			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
SWELLING FACE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
PERINEAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	1	0	2
DYSPHONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	2 / 4 (50.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	4	1	2
EPISTAXIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
OROPHARYNGEAL PAIN			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
PRODUCTIVE COUGH			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DELIRIUM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
HALLUCINATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
RESTLESSNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

TENSION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Product issues			
DEVICE OCCLUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HLA MARKER STUDY POSITIVE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
LYMPHOCYTE COUNT DECREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	5	1
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINE OUTPUT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
WEIGHT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	1	3
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
CHEMICAL PHLEBITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
FOREARM FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
MUSCLE RUPTURE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
MUSCLE STRAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
ATAXIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
DISTURBANCE IN ATTENTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
DYSARTHRIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HEAD DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUSCLE CONTRACTIONS INVOLUNTARY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	2 / 4 (50.00%)	2 / 3 (66.67%)	1 / 4 (25.00%)
occurrences (all)	2	2	1
POLYNEUROPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

PRESYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
SOMNOLENCE			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
TREMOR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	3	1	9
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
NEUTROPENIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	4	0	8
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Ear and labyrinth disorders			
EAR DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
HYPOACUSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
OTOTOXICITY			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
TINNITUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
BLINDNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
VITREOUS DETACHMENT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
ABDOMINAL PAIN UPPER			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
ANAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
CONSTIPATION			
subjects affected / exposed	2 / 4 (50.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
DIARRHOEA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	1	1	4
DIVERTICULUM			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
DRY MOUTH			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
DYSPEPSIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ENTEROVESICAL FISTULA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ERUCTATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
GASTRITIS			

subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LOWER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	2 / 4 (50.00%)
occurrences (all)	1	4	7
OESOPHAGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORAL DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RETCHING			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
STOMATITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	2 / 4 (50.00%)	2 / 3 (66.67%)	3 / 4 (75.00%)
occurrences (all)	2	2	4
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	2 / 4 (50.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	2	1	3
DRY SKIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
ECCHYMOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
NIGHT SWEATS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
PIGMENTATION DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PRURITUS			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
RASH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
STICKY SKIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
DYSURIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
NOCTURIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PNEUMATURIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
POST MICTURITION DRIBBLE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TUBULOINTERSTITIAL NEPHRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINARY HESITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

URINARY RETENTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
BACK PAIN			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
BONE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
COCCYDYNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
GROIN PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
MUSCLE SPASMS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	2	2
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	3 / 4 (75.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
MYOSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NECK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	2 / 4 (50.00%)
occurrences (all)	1	2	2
PAIN IN JAW			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SPINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TENDON PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE COLITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
NASOPHARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORAL FUNGAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
TOOTH ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

URINARY TRACT INFECTION			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	2
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	2 / 4 (50.00%)	2 / 3 (66.67%)	3 / 4 (75.00%)
occurrences (all)	3	4	3
DEHYDRATION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
HYPOMAGNESAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: Veliparib 200 mg BID 7 Days +	Phase 1: Veliparib 240 mg BID 7 Days +	Phase 1: Veliparib 240 mg BID 21 Days +

	Carboplatin/Etoposide	Carboplatin/Etoposide	Carboplatin/Etoposide
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	8 / 8 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
METASTASES TO CENTRAL NERVOUS SYSTEM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
HOT FLUSH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INTERMITTENT CLAUDICATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
CHEST PAIN			

subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
CREPITATIONS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CRYING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
FATIGUE			
subjects affected / exposed	2 / 3 (66.67%)	6 / 8 (75.00%)	1 / 4 (25.00%)
occurrences (all)	4	6	1
FEELING ABNORMAL			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
FEELING COLD			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE EXTRAVASATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE HAEMATOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PHLEBITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LOSS OF CONTROL OF LEGS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NECROSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PYREXIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
SWELLING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SWELLING FACE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Reproductive system and breast disorders			
PERINEAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	2 / 4 (50.00%)
occurrences (all)	1	0	2
DYSPHONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	2 / 4 (50.00%)
occurrences (all)	1	1	2
EPISTAXIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 4 (25.00%)
occurrences (all)	0	1	3
HAEMOPTYSIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
HICCUPS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			

subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
RHINORRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	1 / 3 (33.33%)	2 / 8 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DELIRIUM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
DEPRESSION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HALLUCINATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
INSOMNIA			
subjects affected / exposed	0 / 3 (0.00%)	3 / 8 (37.50%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
RESTLESSNESS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
TENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Product issues			
DEVICE OCCLUSION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Investigations			

ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HLA MARKER STUDY POSITIVE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	2 / 4 (50.00%)
occurrences (all)	2	2	8
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 4 (25.00%)
occurrences (all)	0	1	3
TRANSAMINASES INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINE OUTPUT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
WEIGHT DECREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	2 / 4 (50.00%)
occurrences (all)	1	0	3
Injury, poisoning and procedural complications			
CHEMICAL PHLEBITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FOREARM FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUSCLE RUPTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUSCLE STRAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
PROCEDURAL HEADACHE			

subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
SKIN ABRASION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
PALPITATIONS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
ATAXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
DIZZINESS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	2 / 4 (50.00%)
occurrences (all)	0	4	2
DYSARTHRIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
DYSGEUSIA			

subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	2 / 4 (50.00%)
occurrences (all)	0	1	2
HEAD DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HEADACHE			
subjects affected / exposed	1 / 3 (33.33%)	2 / 8 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
MUSCLE CONTRACTIONS INVOLUNTARY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
POLYNEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	2
TREMOR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	4 / 8 (50.00%)	2 / 4 (50.00%)
occurrences (all)	3	11	6
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
LEUKOPENIA			
subjects affected / exposed	1 / 3 (33.33%)	2 / 8 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	4 / 8 (50.00%)	2 / 4 (50.00%)
occurrences (all)	0	11	6
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	3 / 8 (37.50%)	1 / 4 (25.00%)
occurrences (all)	0	6	3
Ear and labyrinth disorders			
EAR DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
OTOTOXICITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
BLINDNESS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

DRY EYE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
EYE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LACRIMATION INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
VITREOUS DETACHMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
ABDOMINAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 3 (0.00%)	3 / 8 (37.50%)	1 / 4 (25.00%)
occurrences (all)	0	3	3
ANAL INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			

subjects affected / exposed	0 / 3 (0.00%)	3 / 8 (37.50%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
DIARRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
DIVERTICULUM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
DYSPEPSIA			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
DYSPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ENTEROVESICAL FISTULA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

HAEMORRHOIDS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
LOWER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	2 / 3 (66.67%)	5 / 8 (62.50%)	1 / 4 (25.00%)
occurrences (all)	4	8	1
OESOPHAGITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PROCTALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCTITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RETCHING			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
STOMATITIS			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
VOMITING			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	1 / 4 (25.00%)
occurrences (all)	2	2	1
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

ALOPECIA			
subjects affected / exposed	2 / 3 (66.67%)	3 / 8 (37.50%)	1 / 4 (25.00%)
occurrences (all)	2	5	3
DRY SKIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
ECCHYMOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
ECZEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
NIGHT SWEATS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PETECHIAE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PIGMENTATION DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH MACULAR			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
SKIN ULCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

STICKY SKIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
DYSURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NOCTURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PNEUMATURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
POST MICTURITION DRIBBLE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
TUBULOINTERSTITIAL NEPHRITIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
URINARY HESITATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
URINARY RETENTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0

BACK PAIN			
subjects affected / exposed	2 / 3 (66.67%)	2 / 8 (25.00%)	0 / 4 (0.00%)
occurrences (all)	2	3	0
BONE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
COCCYDYNIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
FLANK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
GROIN PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MYALGIA			

subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
MYOSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NECK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
PAIN IN JAW			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SPINAL PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
TENDON PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DEVICE RELATED INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

NASOPHARYNGITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORAL FUNGAL INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
RHINITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 3 (0.00%)	3 / 8 (37.50%)	2 / 4 (50.00%)
occurrences (all)	0	5	2
DEHYDRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			

subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
HYPOCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 4 (25.00%)
occurrences (all)	0	1	3
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
HYPONATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Phase 1: Veliparib 240 mg BID 14 Days + Carboplatin/Etoposide	Phase 2: Veliparib + Carboplatin/Etoposide -> Placebo	Phase 2: Veliparib + Carboplatin/Etoposide -> Veliparib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)	53 / 58 (91.38%)	57 / 60 (95.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0

METASTASES TO CENTRAL NERVOUS SYSTEM			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	0	1	1
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
HOT FLUSH			
subjects affected / exposed	0 / 14 (0.00%)	3 / 58 (5.17%)	0 / 60 (0.00%)
occurrences (all)	0	3	0
HYPERTENSION			
subjects affected / exposed	4 / 14 (28.57%)	1 / 58 (1.72%)	2 / 60 (3.33%)
occurrences (all)	6	3	2
HYPOTENSION			
subjects affected / exposed	1 / 14 (7.14%)	5 / 58 (8.62%)	1 / 60 (1.67%)
occurrences (all)	1	5	1
INTERMITTENT CLAUDICATION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	2 / 14 (14.29%)	11 / 58 (18.97%)	9 / 60 (15.00%)
occurrences (all)	8	26	16
CHEST PAIN			
subjects affected / exposed	1 / 14 (7.14%)	3 / 58 (5.17%)	3 / 60 (5.00%)
occurrences (all)	2	3	3
CREPITATIONS			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
CRYING			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
FATIGUE			

subjects affected / exposed	9 / 14 (64.29%)	16 / 58 (27.59%)	15 / 60 (25.00%)
occurrences (all)	20	17	23
FEELING ABNORMAL			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
FEELING COLD			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	0 / 60 (0.00%)
occurrences (all)	0	3	0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
INJECTION SITE EXTRAVASATION			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
INJECTION SITE HAEMATOMA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PHLEBITIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
LOSS OF CONTROL OF LEGS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	2 / 14 (14.29%)	3 / 58 (5.17%)	0 / 60 (0.00%)
occurrences (all)	3	3	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 14 (7.14%)	2 / 58 (3.45%)	2 / 60 (3.33%)
occurrences (all)	1	2	2
NECROSIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			

subjects affected / exposed	1 / 14 (7.14%)	2 / 58 (3.45%)	1 / 60 (1.67%)
occurrences (all)	1	2	1
OEDEMA			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	3	1	0
OEDEMA PERIPHERAL			
subjects affected / exposed	2 / 14 (14.29%)	6 / 58 (10.34%)	2 / 60 (3.33%)
occurrences (all)	3	7	3
PAIN			
subjects affected / exposed	0 / 14 (0.00%)	3 / 58 (5.17%)	4 / 60 (6.67%)
occurrences (all)	0	3	4
PYREXIA			
subjects affected / exposed	3 / 14 (21.43%)	2 / 58 (3.45%)	6 / 60 (10.00%)
occurrences (all)	3	2	9
SWELLING			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
SWELLING FACE			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	0 / 60 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
PERINEAL PAIN			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	6	0	0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
COUGH			
subjects affected / exposed	5 / 14 (35.71%)	5 / 58 (8.62%)	6 / 60 (10.00%)
occurrences (all)	6	5	6
DYSPHONIA			

subjects affected / exposed	1 / 14 (7.14%)	3 / 58 (5.17%)	2 / 60 (3.33%)
occurrences (all)	1	4	2
DYSPNOEA			
subjects affected / exposed	5 / 14 (35.71%)	9 / 58 (15.52%)	12 / 60 (20.00%)
occurrences (all)	5	11	16
EPISTAXIS			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	1	1	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	2 / 60 (3.33%)
occurrences (all)	0	2	2
HICCUPS			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	2	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 14 (7.14%)	3 / 58 (5.17%)	1 / 60 (1.67%)
occurrences (all)	1	3	1
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 14 (0.00%)	4 / 58 (6.90%)	1 / 60 (1.67%)
occurrences (all)	0	6	1
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	3 / 60 (5.00%)
occurrences (all)	0	2	3
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 14 (0.00%)	3 / 58 (5.17%)	1 / 60 (1.67%)
occurrences (all)	0	3	1
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 14 (0.00%)	4 / 58 (6.90%)	3 / 60 (5.00%)
occurrences (all)	0	4	3
CONFUSIONAL STATE			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	1	1	0

DELIRIUM			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
HALLUCINATION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	7 / 14 (50.00%)	5 / 58 (8.62%)	4 / 60 (6.67%)
occurrences (all)	11	6	5
RESTLESSNESS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
TENSION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
Product issues			
DEVICE OCCLUSION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 14 (7.14%)	3 / 58 (5.17%)	5 / 60 (8.33%)
occurrences (all)	1	6	5
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 14 (7.14%)	3 / 58 (5.17%)	5 / 60 (8.33%)
occurrences (all)	1	4	6
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	2 / 60 (3.33%)
occurrences (all)	0	0	2
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	4 / 60 (6.67%)
occurrences (all)	0	1	4
BLOOD LACTATE DEHYDROGENASE			

INCREASED			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	3 / 60 (5.00%)
occurrences (all)	0	1	3
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
HLA MARKER STUDY POSITIVE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	6 / 14 (42.86%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	20	0	2
PLATELET COUNT DECREASED			
subjects affected / exposed	5 / 14 (35.71%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	11	6	2
TRANSAMINASES INCREASED			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	1	1	0
URINE OUTPUT DECREASED			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	5 / 14 (35.71%)	2 / 58 (3.45%)	3 / 60 (5.00%)
occurrences (all)	13	2	3
WEIGHT INCREASED			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	2 / 60 (3.33%)
occurrences (all)	0	0	3
WHITE BLOOD CELL COUNT DECREASED			

subjects affected / exposed	2 / 14 (14.29%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	2	2	5
Injury, poisoning and procedural complications			
CHEMICAL PHLEBITIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
FOREARM FRACTURE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
MUSCLE RUPTURE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
MUSCLE STRAIN			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL HEADACHE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 14 (0.00%)	5 / 58 (8.62%)	1 / 60 (1.67%)
occurrences (all)	0	5	1
LEFT VENTRICULAR FAILURE			

subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	3 / 60 (5.00%)
occurrences (all)	0	0	4
TACHYCARDIA			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	0	1	1
Nervous system disorders			
ATAXIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
DISTURBANCE IN ATTENTION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	3 / 14 (21.43%)	9 / 58 (15.52%)	5 / 60 (8.33%)
occurrences (all)	6	13	6
DYSARTHRIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	3 / 14 (21.43%)	4 / 58 (6.90%)	2 / 60 (3.33%)
occurrences (all)	3	6	2
HEAD DISCOMFORT			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
HEADACHE			
subjects affected / exposed	3 / 14 (21.43%)	9 / 58 (15.52%)	10 / 60 (16.67%)
occurrences (all)	3	11	11
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
MUSCLE CONTRACTIONS INVOLUNTARY			

subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	3 / 60 (5.00%)
occurrences (all)	0	1	3
POLYNEUROPATHY			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
TREMOR			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	7 / 14 (50.00%)	35 / 58 (60.34%)	35 / 60 (58.33%)
occurrences (all)	18	105	104
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	1	0	1
LEUKOPENIA			

subjects affected / exposed	0 / 14 (0.00%)	12 / 58 (20.69%)	7 / 60 (11.67%)
occurrences (all)	0	27	15
NEUTROPENIA			
subjects affected / exposed	8 / 14 (57.14%)	33 / 58 (56.90%)	36 / 60 (60.00%)
occurrences (all)	34	86	94
THROMBOCYTOPENIA			
subjects affected / exposed	5 / 14 (35.71%)	23 / 58 (39.66%)	22 / 60 (36.67%)
occurrences (all)	16	62	58
Ear and labyrinth disorders			
EAR DISCOMFORT			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
OTOTOXICITY			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	0	1	1
Eye disorders			
BLINDNESS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
EYE IRRITATION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
LACRIMATION INCREASED			

subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
VITREOUS DETACHMENT			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	2	1	0
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	2 / 60 (3.33%)
occurrences (all)	2	1	2
ABDOMINAL PAIN			
subjects affected / exposed	2 / 14 (14.29%)	1 / 58 (1.72%)	4 / 60 (6.67%)
occurrences (all)	2	1	4
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 14 (14.29%)	0 / 58 (0.00%)	2 / 60 (3.33%)
occurrences (all)	2	0	2
ANAL INFLAMMATION			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
ASCITES			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	3 / 14 (21.43%)	13 / 58 (22.41%)	14 / 60 (23.33%)
occurrences (all)	4	19	17
DIARRHOEA			
subjects affected / exposed	7 / 14 (50.00%)	11 / 58 (18.97%)	8 / 60 (13.33%)
occurrences (all)	11	21	11
DIVERTICULUM			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	4 / 14 (28.57%)	3 / 58 (5.17%)	1 / 60 (1.67%)
occurrences (all)	5	4	1

DYSPEPSIA			
subjects affected / exposed	1 / 14 (7.14%)	2 / 58 (3.45%)	7 / 60 (11.67%)
occurrences (all)	1	3	8
DYSPHAGIA			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	2 / 60 (3.33%)
occurrences (all)	1	1	2
ENTEROVESICAL FISTULA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	2 / 14 (14.29%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	3	0	0
FLATULENCE			
subjects affected / exposed	2 / 14 (14.29%)	2 / 58 (3.45%)	0 / 60 (0.00%)
occurrences (all)	2	2	0
GASTRITIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	1 / 60 (1.67%)
occurrences (all)	0	2	2
HAEMATOCHEZIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
LOWER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
NAUSEA			
subjects affected / exposed	9 / 14 (64.29%)	23 / 58 (39.66%)	29 / 60 (48.33%)
occurrences (all)	16	47	57
OESOPHAGITIS			

subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	1	1	2
ORAL DISCOMFORT			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	2	0	0
PROCTITIS			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
RETCHING			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	2	0	0
STOMATITIS			
subjects affected / exposed	2 / 14 (14.29%)	2 / 58 (3.45%)	3 / 60 (5.00%)
occurrences (all)	3	2	4
VOMITING			
subjects affected / exposed	2 / 14 (14.29%)	10 / 58 (17.24%)	13 / 60 (21.67%)
occurrences (all)	3	12	20
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	8 / 14 (57.14%)	17 / 58 (29.31%)	22 / 60 (36.67%)
occurrences (all)	12	19	27
DRY SKIN			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
ECCHYMOSIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
ECZEMA			

subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
HYPERHIDROSIS			
subjects affected / exposed	3 / 14 (21.43%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	4	0	1
NIGHT SWEATS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
PETECHIAE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
PIGMENTATION DISORDER			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
PRURITUS			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	1	2	1
RASH			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	4 / 60 (6.67%)
occurrences (all)	1	1	4
RASH MACULAR			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
SKIN ULCER			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
STICKY SKIN			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
DYSURIA			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
NOCTURIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0

PNEUMATURIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
POST MICTURITION DRIBBLE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
TUBULOINTERSTITIAL NEPHRITIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
URINARY HESITATION			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	1	1	2
Endocrine disorders			
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 14 (7.14%)	2 / 58 (3.45%)	6 / 60 (10.00%)
occurrences (all)	4	6	8
BACK PAIN			
subjects affected / exposed	6 / 14 (42.86%)	7 / 58 (12.07%)	9 / 60 (15.00%)
occurrences (all)	6	7	11
BONE PAIN			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	3 / 60 (5.00%)
occurrences (all)	0	1	3
COCCYDYNIA			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			

subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	1	0	1
GROIN PAIN			
subjects affected / exposed	2 / 14 (14.29%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	2	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	2 / 60 (3.33%)
occurrences (all)	0	0	2
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	0 / 60 (0.00%)
occurrences (all)	0	2	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 14 (7.14%)	3 / 58 (5.17%)	5 / 60 (8.33%)
occurrences (all)	1	7	5
MUSCULOSKELETAL PAIN			
subjects affected / exposed	2 / 14 (14.29%)	2 / 58 (3.45%)	3 / 60 (5.00%)
occurrences (all)	3	2	3
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
MYALGIA			
subjects affected / exposed	2 / 14 (14.29%)	2 / 58 (3.45%)	1 / 60 (1.67%)
occurrences (all)	2	8	1
MYOSITIS			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
NECK PAIN			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	3 / 60 (5.00%)
occurrences (all)	0	1	4
PAIN IN EXTREMITY			
subjects affected / exposed	4 / 14 (28.57%)	4 / 58 (6.90%)	1 / 60 (1.67%)
occurrences (all)	6	4	2

PAIN IN JAW			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	1 / 60 (1.67%)
occurrences (all)	1	0	1
SPINAL PAIN			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
TENDON PAIN			
subjects affected / exposed	1 / 14 (7.14%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 14 (0.00%)	3 / 58 (5.17%)	1 / 60 (1.67%)
occurrences (all)	0	3	1
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	1	1	0
CYSTITIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	1 / 14 (7.14%)	2 / 58 (3.45%)	2 / 60 (3.33%)
occurrences (all)	1	3	2
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 14 (7.14%)	4 / 58 (6.90%)	1 / 60 (1.67%)
occurrences (all)	1	4	2
ORAL FUNGAL INFECTION			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			

subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	5 / 60 (8.33%)
occurrences (all)	0	0	5
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 14 (0.00%)	3 / 58 (5.17%)	1 / 60 (1.67%)
occurrences (all)	0	3	1
RHINITIS			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	0	1	1
TOOTH ABSCESS			
subjects affected / exposed	0 / 14 (0.00%)	0 / 58 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 14 (14.29%)	2 / 58 (3.45%)	0 / 60 (0.00%)
occurrences (all)	2	2	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 14 (7.14%)	2 / 58 (3.45%)	1 / 60 (1.67%)
occurrences (all)	1	3	1
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	7 / 14 (50.00%)	12 / 58 (20.69%)	17 / 60 (28.33%)
occurrences (all)	16	14	20
DEHYDRATION			
subjects affected / exposed	0 / 14 (0.00%)	3 / 58 (5.17%)	1 / 60 (1.67%)
occurrences (all)	0	3	1
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 14 (7.14%)	6 / 58 (10.34%)	1 / 60 (1.67%)
occurrences (all)	1	6	1
HYPERKALAEMIA			
subjects affected / exposed	0 / 14 (0.00%)	2 / 58 (3.45%)	2 / 60 (3.33%)
occurrences (all)	0	2	2
HYPOCALCAEMIA			
subjects affected / exposed	0 / 14 (0.00%)	3 / 58 (5.17%)	2 / 60 (3.33%)
occurrences (all)	0	3	2
HYPOGLYCAEMIA			

subjects affected / exposed	1 / 14 (7.14%)	1 / 58 (1.72%)	0 / 60 (0.00%)
occurrences (all)	1	1	0
HYPOKALAEMIA			
subjects affected / exposed	1 / 14 (7.14%)	9 / 58 (15.52%)	5 / 60 (8.33%)
occurrences (all)	2	13	5
HYPOMAGNESAEMIA			
subjects affected / exposed	4 / 14 (28.57%)	7 / 58 (12.07%)	10 / 60 (16.67%)
occurrences (all)	5	9	24
HYPONATRAEMIA			
subjects affected / exposed	1 / 14 (7.14%)	7 / 58 (12.07%)	6 / 60 (10.00%)
occurrences (all)	3	7	8
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 14 (0.00%)	1 / 58 (1.72%)	1 / 60 (1.67%)
occurrences (all)	0	1	1

Non-serious adverse events	Phase 2: Placebo + Carboplatin/Etoposide -> Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 60 (88.33%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
METASTASES TO CENTRAL NERVOUS SYSTEM			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
HOT FLUSH			

subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
HYPERTENSION			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	3		
HYPOTENSION			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
INTERMITTENT CLAUDICATION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	3		
CHEST PAIN			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
CREPITATIONS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
CRYING			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
FACE OEDEMA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
FATIGUE			
subjects affected / exposed	10 / 60 (16.67%)		
occurrences (all)	12		
FEELING ABNORMAL			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
FEELING COLD			

subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
GAIT DISTURBANCE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
INFLUENZA LIKE ILLNESS				
subjects affected / exposed	2 / 60 (3.33%)			
occurrences (all)	2			
INJECTION SITE EXTRAVASATION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
INJECTION SITE HAEMATOMA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
INJECTION SITE PHLEBITIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
LOSS OF CONTROL OF LEGS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
MALAISE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
MUCOSAL INFLAMMATION				
subjects affected / exposed	3 / 60 (5.00%)			
occurrences (all)	3			
NECROSIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
NON-CARDIAC CHEST PAIN				
subjects affected / exposed	4 / 60 (6.67%)			
occurrences (all)	4			
OEDEMA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
OEDEMA PERIPHERAL				

subjects affected / exposed	5 / 60 (8.33%)		
occurrences (all)	5		
PAIN			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	3		
PYREXIA			
subjects affected / exposed	8 / 60 (13.33%)		
occurrences (all)	10		
SWELLING			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
SWELLING FACE			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
PERINEAL PAIN			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
COUGH			
subjects affected / exposed	7 / 60 (11.67%)		
occurrences (all)	7		
DYSPHONIA			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
DYSPNOEA			
subjects affected / exposed	7 / 60 (11.67%)		
occurrences (all)	10		
EPISTAXIS			

subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
HAEMOPTYSIS			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	3		
HICCUPS			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
OROPHARYNGEAL PAIN			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
PRODUCTIVE COUGH			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	3		
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
RHINORRHOEA			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	4		
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
CONFUSIONAL STATE			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
DELIRIUM			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
DEPRESSION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		

HALLUCINATION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
INSOMNIA			
subjects affected / exposed	4 / 60 (6.67%)		
occurrences (all)	4		
RESTLESSNESS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
TENSION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Product issues			
DEVICE OCCLUSION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	10		
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	3		
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	3		
BLOOD CREATININE INCREASED			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
GAMMA-GLUTAMYLTRANSFERASE INCREASED			

subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
HLA MARKER STUDY POSITIVE			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
URINE OUTPUT DECREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
WEIGHT DECREASED			
subjects affected / exposed	7 / 60 (11.67%)		
occurrences (all)	11		
WEIGHT INCREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			

CHEMICAL PHLEBITIS subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
FOREARM FRACTURE subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
INFUSION RELATED REACTION subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
MUSCLE RUPTURE subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
MUSCLE STRAIN subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
POST PROCEDURAL COMPLICATION subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
PROCEDURAL HEADACHE subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
PROCEDURAL PAIN subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
SKIN ABRASION subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
Cardiac disorders ATRIAL FIBRILLATION subjects affected / exposed occurrences (all)	1 / 60 (1.67%) 1		
LEFT VENTRICULAR FAILURE subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
PALPITATIONS			

subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
TACHYCARDIA			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
Nervous system disorders			
ATAXIA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
DISTURBANCE IN ATTENTION			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	2		
DIZZINESS			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	4		
DYSARTHRIA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
DYSGEUSIA			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
HEAD DISCOMFORT			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
HEADACHE			
subjects affected / exposed	7 / 60 (11.67%)		
occurrences (all)	7		
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
MUSCLE CONTRACTIONS INVOLUNTARY			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
NEUROPATHY PERIPHERAL			

subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
POLYNEUROPATHY			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PRESYNCOPE			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
SOMNOLENCE			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
TREMOR			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	26 / 60 (43.33%)		
occurrences (all)	55		
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
FEBRILE NEUTROPENIA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
LEUKOPENIA			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	13		
NEUTROPENIA			

subjects affected / exposed	28 / 60 (46.67%)		
occurrences (all)	71		
THROMBOCYTOPENIA			
subjects affected / exposed	12 / 60 (20.00%)		
occurrences (all)	22		
Ear and labyrinth disorders			
EAR DISCOMFORT			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
HYPOACUSIS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
OTOTOXICITY			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
TINNITUS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Eye disorders			
BLINDNESS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
DRY EYE			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
EYE IRRITATION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
EYE PAIN			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
LACRIMATION INCREASED			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
VITREOUS DETACHMENT			

subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
ABDOMINAL PAIN			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	3		
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
ANAL INFLAMMATION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
ASCITES			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
CONSTIPATION			
subjects affected / exposed	11 / 60 (18.33%)		
occurrences (all)	15		
DIARRHOEA			
subjects affected / exposed	11 / 60 (18.33%)		
occurrences (all)	12		
DIVERTICULUM			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
DRY MOUTH			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
DYSPEPSIA			
subjects affected / exposed	4 / 60 (6.67%)		
occurrences (all)	5		

DYSPHAGIA				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
ENTEROVESICAL FISTULA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
ERUCTATION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
FLATULENCE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
GASTRITIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
GASTROOESOPHAGEAL REFLUX DISEASE				
subjects affected / exposed	3 / 60 (5.00%)			
occurrences (all)	3			
HAEMATOCHEZIA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
HAEMORRHOIDS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
LOWER GASTROINTESTINAL HAEMORRHAGE				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
NAUSEA				
subjects affected / exposed	21 / 60 (35.00%)			
occurrences (all)	29			
OESOPHAGITIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
ORAL DISCOMFORT				

subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PROCTALGIA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PROCTITIS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
RETCHING			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
STOMATITIS			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	4		
VOMITING			
subjects affected / exposed	8 / 60 (13.33%)		
occurrences (all)	9		
Hepatobiliary disorders			
HEPATIC PAIN			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	18 / 60 (30.00%)		
occurrences (all)	20		
DRY SKIN			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
ECCHYMOSIS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
ECZEMA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
HYPERHIDROSIS			

subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
NIGHT SWEATS			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
PETECHIAE			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PIGMENTATION DISORDER			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PRURITUS			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
RASH			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
RASH MACULAR			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
SKIN ULCER			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
STICKY SKIN			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
DYSURIA			
subjects affected / exposed	2 / 60 (3.33%)		
occurrences (all)	2		
NOCTURIA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PNEUMATURIA			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		

POST MICTURITION DRIBBLE subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
TUBULOINTERSTITIAL NEPHRITIS subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
URINARY HESITATION subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
URINARY INCONTINENCE subjects affected / exposed occurrences (all)	1 / 60 (1.67%) 1		
URINARY RETENTION subjects affected / exposed occurrences (all)	1 / 60 (1.67%) 1		
Endocrine disorders INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
Musculoskeletal and connective tissue disorders ARTHRALGIA subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
BACK PAIN subjects affected / exposed occurrences (all)	9 / 60 (15.00%) 9		
BONE PAIN subjects affected / exposed occurrences (all)	3 / 60 (5.00%) 3		
COCCYDYNIA subjects affected / exposed occurrences (all)	0 / 60 (0.00%) 0		
FLANK PAIN subjects affected / exposed occurrences (all)	2 / 60 (3.33%) 2		
GROIN PAIN			

subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
INTERVERTEBRAL DISC PROTRUSION				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
MUSCLE SPASMS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
MUSCULAR WEAKNESS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
MUSCULOSKELETAL CHEST PAIN				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
MUSCULOSKELETAL PAIN				
subjects affected / exposed	2 / 60 (3.33%)			
occurrences (all)	2			
MUSCULOSKELETAL STIFFNESS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
MYALGIA				
subjects affected / exposed	4 / 60 (6.67%)			
occurrences (all)	4			
MYOSITIS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
NECK PAIN				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
PAIN IN EXTREMITY				
subjects affected / exposed	2 / 60 (3.33%)			
occurrences (all)	2			
PAIN IN JAW				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			

SPINAL PAIN			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
TENDON PAIN			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
CYSTITIS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
GASTROENTERITIS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
NASOPHARYNGITIS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
ORAL FUNGAL INFECTION			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
PNEUMONIA			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	3		
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
RHINITIS				
subjects affected / exposed	2 / 60 (3.33%)			
occurrences (all)	2			
TOOTH ABSCESS				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
UPPER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	2 / 60 (3.33%)			
occurrences (all)	2			
URINARY TRACT INFECTION				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Metabolism and nutrition disorders				
DECREASED APPETITE				
subjects affected / exposed	14 / 60 (23.33%)			
occurrences (all)	16			
DEHYDRATION				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
HYPERGLYCAEMIA				
subjects affected / exposed	6 / 60 (10.00%)			
occurrences (all)	7			
HYPERKALAEMIA				
subjects affected / exposed	3 / 60 (5.00%)			
occurrences (all)	6			
HYPOCALCAEMIA				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
HYPOGLYCAEMIA				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
HYPOKALAEMIA				

subjects affected / exposed	7 / 60 (11.67%)		
occurrences (all)	8		
HYPOMAGNESAEMIA			
subjects affected / exposed	9 / 60 (15.00%)		
occurrences (all)	12		
HYPONATRAEMIA			
subjects affected / exposed	4 / 60 (6.67%)		
occurrences (all)	5		
HYPOPHOSPHATAEMIA			
subjects affected / exposed	5 / 60 (8.33%)		
occurrences (all)	6		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 May 2015	Allowed any advanced/metastatic solid tumors for which carboplatin/etoposide is appropriate. Changed window for baseline radiographic tumor assessments from 14 days to 21 days. Clarified plan for replacement of subjects in the Phase 1 dose-escalation portion of the study. Updated the statistical analysis for Phase 2 and clarified plan for discontinuation of Phase 2 subjects from treatment vs. study. Added DMC to Phase 2 portion of the study.
30 July 2015	Clarified enrollment and timing of dose escalations during the Phase 1 portion of the study and allow for additional subjects for safety expansion at the RPTD. Clarified PK sampling schedule. Corrected the time of contraceptive use following the last dose of the study drug.
18 December 2015	Added additional DLT criteria and updated the total number of subjects in the Phase 1 dose-escalation portion of the study. Updated language around new veliparib dosing schedules. Added language to allow for Phase 2 subjects who discontinued carboplatin and etoposide due to toxicity but not disease progression to transition to monotherapy veliparib or placebo. Updated the length of time that subjects were followed on study to "until disease progression."
14 June 2016	Increased total number of carboplatin, etoposide and veliparib cycles for Phase 2 subjects. Changed Cycle 5 to Maintenance for Phase 2. Increased total number of subjects and sites.
22 November 2016	Added veliparib/placebo RPTD of 240 mg BID in a 14-day schedule as the veliparib/placebo dose and schedule for Phase 2 combination therapy.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30327308