



Clinical trial results:

A PHASE I STUDY OF PAZOPANIB AS A SINGLE AGENT FOR CHILDREN WITH RELAPSED OR REFRACTORY SOLID TUMORS, INCLUDING CNS TUMORS

Summary

EudraCT number	2012-001306-20
Trial protocol	Outside EU/EEA
Global end of trial date	03 January 2013

Results information

Result version number	v1 (current)
This version publication date	01 May 2017
First version publication date	01 May 2017

Trial information

Trial identification

Sponsor protocol code	ADVL0815
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Glaxo Group Limited: PZP114411

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	Julia Glade-Bender, MD, Columbia University Medical Center - Pediatric Oncology, 001 (212)305-58083379, jg589@columbia.edu
Scientific contact	Julia Glade-Bender, MD, Columbia University Medical Center - Pediatric Oncology, 001 (212)305-58083379, jg589@columbia.edu

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-000601-PIP01-09
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	26 April 2013
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	03 January 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. To estimate the maximum tolerated dose (MTD) and/or recommended Phase II dose of oral pazopanib administered on a once daily schedule to children with refractory solid tumors.
2. To define and describe the toxicities of oral pazopanib administered as either a tablet or suspension.
3. To characterize the pharmacokinetics of oral pazopanib in children with refractory solid tumors.

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 53
Worldwide total number of subjects	53
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	22
Adolescents (12-17 years)	20
Adults (18-64 years)	11
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was conducted in 3 parts: Part 1 (Phase I Dose Escalation), Part 2a (Suspension Formulation Component) and Part 2b (Expanded Imaging Cohort).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: Pazopanib 275 mg/m ²

Arm description:

In the Phase I part, participants received pazopanib tablets 275 milligrams (mg)/square meter (m²), orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Arm type	Experimental
Investigational medicinal product name	Pazopanib 275 mg/m ²
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Pazopanib tablets at a dose of 275 mg/m² orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles.

Arm title	Part 1: Pazopanib 350 mg/m ²
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Arm description:

In the Phase I part, participants received pazopanib tablets 350 mg/m², orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Arm type	Experimental
Investigational medicinal product name	Pazopanib 350 mg/m ²
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Pazopanib tablets at a dose of 350 mg/m².

Arm title	Part 1: Pazopanib 450 mg/m ²
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Arm description:

In the Phase I part, participants received pazopanib tablets 450 mg/m², orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an

empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Arm type	Experimental
Investigational medicinal product name	Pazopanib 450 mg/m ²
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Pazopanib tablets at a dose of 450 mg/m².

Arm title	Part 1: Pazopanib 600 mg/m ²
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Arm description:

In the Phase I part, participants received pazopanib tablets 600 mg/m², orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Arm type	Experimental
Investigational medicinal product name	Pazopanib 600 mg/m ²
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Pazopanib tablets at a dose of 600 mg/m²

Arm title	Part 2a: Pazopanib OS 160 mg/m ²
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Arm description:

In the Phase 2a part, participants received pazopanib suspension at a dose of 160 mg/m². The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time.

Arm type	Experimental
Investigational medicinal product name	Pazopanib OS 160 mg/m ²
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Pazopanib suspension formulation at a dose of 160 mg/m².

Arm title	Part 2a: Pazopanib OS 225 mg/m ²
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Arm description:

In the Phase 2a part, participants received pazopanib suspension formulation of 225 mg/m². The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time.

Arm type	Experimental
Investigational medicinal product name	Pazopanib OS 225 mg/m ²
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Pazopanib suspension formulation at a dose of 225 mg/m².

Arm title	Part 2b: Pazopanib 450 mg/m ²
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Arm description:

In the Phase 2b part, participants received pazopanib tablets of 450 mg/m². The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time with clear liquids.

Arm type	Experimental
Investigational medicinal product name	Pazopanib 450 mg/m ²
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Pazopanib tablets at a dose of 450 mg/m².

Number of subjects in period 1	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²
Started	7	6	7
Completed	0	0	0
Not completed	7	6	7
Completion of 24 Cycles per Protocol	-	-	-
Adverse event, non-fatal	2	-	3
Refusal of Further Protocol Therapy	1	1	1
due to disease progression	4	5	3

Number of subjects in period 1	Part 1: Pazopanib 600 mg/m ²	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²
Started	7	12	4
Completed	0	0	0
Not completed	7	12	4
Completion of 24 Cycles per Protocol	-	-	-
Adverse event, non-fatal	1	1	3
Refusal of Further Protocol Therapy	1	1	-
due to disease progression	5	10	1

Number of subjects in period 1	Part 2b: Pazopanib 450 mg/m ²
Started	10
Completed	0
Not completed	10

Completion of 24 Cycles per Protocol	1
Adverse event, non-fatal	1
Refusal of Further Protocol Therapy	1
due to disease progression	7

Baseline characteristics

Reporting groups

Reporting group title	Part 1: Pazopanib 275 mg/m ²
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Reporting group description:

In the Phase I part, participants received pazopanib tablets 275 milligrams (mg)/square meter (m²), orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Reporting group title	Part 1: Pazopanib 350 mg/m ²
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Reporting group description:

In the Phase I part, participants received pazopanib tablets 350 mg/m², orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Reporting group title	Part 1: Pazopanib 450 mg/m ²
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Reporting group description:

In the Phase I part, participants received pazopanib tablets 450 mg/m², orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Reporting group title	Part 1: Pazopanib 600 mg/m ²
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Reporting group description:

In the Phase I part, participants received pazopanib tablets 600 mg/m², orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Reporting group title	Part 2a: Pazopanib OS 160 mg/m ²
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Reporting group description:

In the Phase 2a part, participants received pazopanib suspension at a dose of 160 mg/m². The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time.

Reporting group title	Part 2a: Pazopanib OS 225 mg/m ²
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Reporting group description:

In the Phase 2a part, participants received pazopanib suspension formulation of 225 mg/m². The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time.

Reporting group title	Part 2b: Pazopanib 450 mg/m ²
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Reporting group description:

In the Phase 2b part, participants received pazopanib tablets of 450 mg/m². The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time with clear liquids.

Reporting group values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²
Number of subjects	7	6	7
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	13.9 ± 4.88	10 ± 3.22	15 ± 3.96
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Gender categorical Units: Subjects			
Female	3	3	3
Male	4	3	4
Race Customized Units: Subjects			
Black	2	1	1
Korean	0	1	0
Other Asian	0	0	0
White	5	4	6
Unknown	0	0	0

Reporting group values	Part 1: Pazopanib 600 mg/m ²	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²
Number of subjects	7	12	4
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	13.6	12.8	7
standard deviation	± 5.13	± 4.73	± 3.56
Gender categorical Units: Subjects			
Female	4	6	2
Male	3	6	2
Race Customized Units: Subjects			
Black	0	2	1
Korean	0	0	0
Other Asian	1	0	0
White	5	10	3
Unknown	1	0	0

Reporting group values	Part 2b: Pazopanib 450 mg/m ²	Total	
Number of subjects	10	53	
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	15.5		
standard deviation	± 4.6	-	
Gender categorical Units: Subjects			
Female	5	26	
Male	5	27	
Race Customized Units: Subjects			
Black	0	7	
Korean	0	1	

Other Asian	0	1	
White	9	42	
Unknown	1	2	

End points

End points reporting groups

Reporting group title	Part 1: Pazopanib 275 mg/m ²
Reporting group description: In the Phase I part, participants received pazopanib tablets 275 milligrams (mg)/square meter (m ²), orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.	
Reporting group title	Part 1: Pazopanib 350 mg/m ²
Reporting group description: In the Phase I part, participants received pazopanib tablets 350 mg/m ² , orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.	
Reporting group title	Part 1: Pazopanib 450 mg/m ²
Reporting group description: In the Phase I part, participants received pazopanib tablets 450 mg/m ² , orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.	
Reporting group title	Part 1: Pazopanib 600 mg/m ²
Reporting group description: In the Phase I part, participants received pazopanib tablets 600 mg/m ² , orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.	
Reporting group title	Part 2a: Pazopanib OS 160 mg/m ²
Reporting group description: In the Phase 2a part, participants received pazopanib suspension at a dose of 160 mg/m ² . The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time.	
Reporting group title	Part 2a: Pazopanib OS 225 mg/m ²
Reporting group description: In the Phase 2a part, participants received pazopanib suspension formulation of 225 mg/m ² . The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time.	
Reporting group title	Part 2b: Pazopanib 450 mg/m ²
Reporting group description: In the Phase 2b part, participants received pazopanib tablets of 450 mg/m ² . The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time with clear liquids.	
Subject analysis set title	Part 1: Pazopanib Tablet
Subject analysis set type	Sub-group analysis
Subject analysis set description: In the Phase I part, participants received pazopanib tablets 275 or 350 or 450 or 600 mg/m ² , orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.	
Subject analysis set title	Part 2: Pazopanib OS
Subject analysis set type	Sub-group analysis
Subject analysis set description: In the Phase 2a part, participants received pazopanib suspension at a dose of 160 or 225 mg/m ² . The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time.	

Primary: Number of participants experiencing a Dose-limiting Toxicity (DLT) during Cycle 1

End point title	Number of participants experiencing a Dose-limiting Toxicity (DLT) during Cycle 1 ^[1]
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End point description:

A DLT was defined as an event that was at least (possibly, probably, or definitely) attributable to pazopanib, and met any of the following criteria, according to National Cancer Institutes (NCI) common terminology criteria for AE (CTCAE) grade (G) version 4.0 (with certain study-defined exclusions): A) Non-hematological DLT: Any G4 or G3 non-hematological toxicity; G2 non-hematological toxicity ≥ 7 days; G2 ALT elevation in the presence of a G2 total bilirubin (sum of conjugated + unconjugated) elevation with direct bilirubin $> 35\%$ of total bilirubin; dose-limiting hypertension; B) Hematological DLT: G4 thrombocytopenia (platelet count $< 25,000/\text{mm}^3$) or G4 neutropenia; any hematologic toxicity requiring treatment interruption for > 14 days or a dose reduction; \geq G2 arterial thromboembolic events (visceral arterial ischemia, peripheral ischemia, or ischemia cerebrovascular); \geq G3 venous thromboembolic event; any thrombotic event requiring systemic anticoagulation.

End point type	Primary
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End point timeframe:

Up to 28 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: There are no statistical data to report.

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7 ^[2]	6 ^[3]	7 ^[4]	7 ^[5]
Units: Participants	1	0	1	2

Notes:

[2] - Safety Population: all participants who received at least one dose of pazopanib.

[3] - Safety Population: all participants who received at least one dose of pazopanib.

[4] - Safety Population: all participants who received at least one dose of pazopanib.

[5] - Safety Population: all participants who received at least one dose of pazopanib.

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12 ^[6]	4 ^[7]	0 ^[8]	
Units: Participants	1	2		

Notes:

[6] - Safety Population: all participants who received at least one dose of pazopanib.

[7] - Safety Population: all participants who received at least one dose of pazopanib.

[8] - Safety Population: all participants who received at least one dose of pazopanib.

Statistical analyses

No statistical analyses for this end point

Primary: Maximum tolerated dose (MTD) for Part 1 and 2

End point title	Maximum tolerated dose (MTD) for Part 1 and 2 ^[9]
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End point description:

The MTD was defined as the highest dose level at which fewer than one third of patients experienced DLT.

End point type	Primary
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End point timeframe:

Up to 28 days

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: There are no statistical data to report.

End point values	Part 1: Pazopanib Tablet	Part 2: Pazopanib OS		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	27 ^[10]	26 ^[11]		
Units: mg/m ²				
number (not applicable)	450	160		

Notes:

[10] - Safety Population

[11] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Outcome Measure Title 3. Number of participants with any adverse event (AE) and serious adverse event (SAE)

End point title	Outcome Measure Title 3. Number of participants with any adverse event (AE) and serious adverse event (SAE) ^[12]
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End point description:

An AE was defined as any untoward medical occurrence in a participant temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. An SAE was defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, is an important medical event that jeopardizes the participants or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition, or is associated with liver injury and impaired liver function.

End point type	Primary
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End point timeframe:

30 days after last dose of study treatment (maximum of approximately 13 months)

Notes:

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

Justification: There are no statistical data to report.

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7 ^[13]	6 ^[14]	7 ^[15]	7 ^[16]
Units: Participants				
Any AE	7	6	7	7
Any SAE	4	2	3	5

Notes:

[13] - Safety Population

[14] - Safety Population

[15] - Safety Population

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12 ^[17]	4 ^[18]	10 ^[19]	
Units: Participants				
Any AE	12	4	10	
Any SAE	4	2	5	

Notes:

[17] - Safety Population

[18] - Safety Population

[19] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Area under the plasma concentration-time curve (AUC) from time zero to eight hours (AUC [0-8]) and AUC from time zero to 24 hours [AUC(0-24)] of pazopanib

End point title	Area under the plasma concentration-time curve (AUC) from time zero to eight hours (AUC [0-8]) and AUC from time zero to 24 hours [AUC(0-24)] of pazopanib ^[20]
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End point description:

Plasma samples were collected at indicated time points to evaluate AUC [0-8] and AUC [0-24] of pazopanib. Geometric mean and coefficient of variation were calculated. PK Population consisted of all participants in the Safety Population for whom a PK sample was obtained and analyzed. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). 99999 indicate that data were not available.

End point type	Primary
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End point timeframe:

Pre-dose, 30 min, 1 hour (h), 2h, 4h, 6h, 8h, 10-12 h and 24 h post-dose at Day 1 and pre-dose, 1 h, 2h, 4h, 6h, 8h at Day 15/22 of Cycle 1

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: There are no statistical data to report.

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[21]	6 ^[22]	5 ^[23]	5 ^[24]
Units: Hour (h)*microgram (µg)/milliliter (mL)				
geometric mean (geometric coefficient of variation)				
AUC(0-8), Day 1, n= 5,2,2,3,12,4,3	164.469 (± 47.845)	113.999 (± 115.902)	261.112 (± 95.605)	257.175 (± 80.394)
AUC(0-8), Day 15/22, n=5,1,2,3,10,2,3	304.074 (± 18.851)	61.395 (± 99999)	364.698 (± 53.083)	587.803 (± 25.118)
AUC(0-24), Day 1, n= 5,2,2,3,10,4,3	431.465 (± 50.358)	241.997 (± 124.582)	664.096 (± 105.675)	747.591 (± 59.577)

Notes:

[21] - PK Population

[22] - PK Population

[23] - PK Population

[24] - PK Population

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12 ^[25]	4 ^[26]	8 ^[27]	
Units: Hour (h)*microgram (µg)/milliliter (mL)				
geometric mean (geometric coefficient of variation)				
AUC(0-8), Day 1, n= 5,2,2,3,12,4,3	113.518 (± 53.909)	164.351 (± 44.375)	115.42 (± 28.342)	
AUC(0-8), Day 15/22, n=5,1,2,3,10,2,3	241.13 (± 35.825)	291.38 (± 23.047)	305.747 (± 43.512)	
AUC(0-24), Day 1, n= 5,2,2,3,10,4,3	341.807 (± 65.711)	376.839 (± 47.728)	348.591 (± 44.258)	

Notes:

[25] - PK Population

[26] - PK Population

[27] - PK Population

Statistical analyses

No statistical analyses for this end point

Primary: Evaluation of maximum observed plasma drug concentration (C_{max}) and last observed quantifiable concentration (C_{last}) of pazopanib

End point title	Evaluation of maximum observed plasma drug concentration (C _{max}) and last observed quantifiable concentration (C _{last}) of pazopanib ^[28]
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End point description:

Plasma samples were collected at indicated time points to evaluate AUC [0-8] and AUC [0-24] of pazopanib. Geometric mean and coefficient of variation were calculated. PK Population consisted of all participants in the Safety Population for whom a PK sample was obtained and analyzed. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). 99999 indicate that data were not available.

End point type	Primary
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End point timeframe:

Pre-dose, 30 min, 1 hour (h), 2h, 4h, 6h, 8h, 10-12 h and 24 h post-dose at Day 1 and pre-dose, 1 h, 2h, 4h, 6h, 8h at Day 15/22 of Cycle 1

Notes:

[28] - 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: There are no statistical data to report.

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[29]	6 ^[30]	5 ^[31]	5 ^[32]
Units: micrograms per millilitre (µg/mL)				
geometric mean (geometric coefficient of variation)				

Cmax, Day 1, n=5,2,2,3,12,4,3	32.954 (± 45.24)	22.384 (± 108.092)	48.466 (± 97.081)	48.592 (± 66.539)
Cmax, Day 15/22, n=5,1,2,3,10,2,3	47.302 (± 26.914)	11.611 (± 99999)	56.687 (± 45.35)	84.631 (± 24.573)
Clast, Day 1, n=5,2,2,3,12,4,3	13.851 (± 52.252)	3.93 (± 132.287)	18.388 (± 106.944)	22.092 (± 36.375)

Notes:

[29] - PK Population

[30] - PK Population

[31] - PK Population

[32] - PK Population

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12 ^[33]	4 ^[34]	8 ^[35]	
Units: micrograms per millilitre (µg/mL)				
geometric mean (geometric coefficient of variation)				
Cmax, Day 1, n=5,2,2,3,12,4,3	19.731 (± 60.175)	27.759 (± 45.97)	20.485 (± 35.501)	
Cmax, Day 15/22, n=5,1,2,3,10,2,3	37.392 (± 33.716)	45.596 (± 18.413)	42.459 (± 43.54)	
Clast, Day 1, n=5,2,2,3,12,4,3	10.224 (± 83.305)	8.419 (± 51.107)	11.353 (± 58.642)	

Notes:

[33] - PK Population

[34] - PK Population

[35] - PK Population

Statistical analyses

No statistical analyses for this end point

Primary: Time to reach maximum plasma concentration (tmax) of pazopanib

End point title	Time to reach maximum plasma concentration (tmax) of pazopanib ^[36]
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End point description:

Plasma samples were collected at indicated time points to evaluate tmax. T max was defined as time to reach Cmax (h), determined directly from the concentration-time data. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).99999 indicate that data were not available.

End point type	Primary
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End point timeframe:

Pre-dose, 30 min, 1 hour (h), 2h, 4h, 6h, 8h, 10-12 h and 24 h post-dose at Day 1 and pre-dose, 1 h, 2h, 4h, 6h, 8h at Day 15/22 of Cycle 1

Notes:

[36] - 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: There are no statistical data to report.

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6 ^[37]	6 ^[38]	5 ^[39]	5 ^[40]
Units: hour				
arithmetic mean (standard deviation)				
tmax, Day 1, n=5,2,2,3,12,4,3	7.573 (± 8.4346)	3.492 (± 3.5237)	4.042 (± 2.7695)	6.08 (± 2.0371)
tmax, Day 15/22, n=5,1,2,3,10,2,3	2.228 (± 1.0964)	2 (± 99999)	3.5 (± 3.5355)	4.843 (± 2.4037)

Notes:

[37] - PK Population

[38] - PK Population

[39] - PK Population

[40] - PK Population

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12 ^[41]	4 ^[42]	8 ^[43]	
Units: hour				
arithmetic mean (standard deviation)				
tmax, Day 1, n=5,2,2,3,12,4,3	3.826 (± 3.018)	3.018 (± 1.9884)	5.361 (± 4.2101)	
tmax, Day 15/22, n=5,1,2,3,10,2,3	3.418 (± 2.5862)	2.017 (± 0.0471)	2 (± 1.7321)	

Notes:

[41] - PK Population

[42] - PK Population

[43] - PK Population

Statistical analyses

No statistical analyses for this end point

Primary: Terminal phase half-life (t_{1/2}) of pazopanib

End point title	Terminal phase half-life (t _{1/2}) of pazopanib ^[44]
End point description:	
Plasma samples were collected at indicated time points to evaluate t _{1/2} . T _{1/2} was defined as time taken to reach the concentration levels to fall to 50%. Geometric mean and coefficient of variation were calculated.	
End point type	Primary
End point timeframe:	
Pre-dose, 30 min, 1 hour (h), 2h, 4h, 6h, 8h, 10-12 h and 24 h post-dose at Day 1 and pre-dose, 1 h, 2h, 4h, 6h, 8h at Day 15/22 of Cycle 1	

Notes:

[44] - 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: There are no statistical data to report.

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[45]	2 ^[46]	2 ^[47]	3 ^[48]
Units: hour				
geometric mean (geometric coefficient of variation)	16.608 (± 28.775)	10.625 (± 33.101)	17.9 (± 39.765)	13.356 (± 32.264)

Notes:

[45] - PK Population

[46] - PK Population

[47] - PK Population

[48] - PK Population

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10 ^[49]	4 ^[50]	3 ^[51]	
Units: hour				
geometric mean (geometric coefficient of variation)	22.394 (± 71.724)	13.003 (± 16.394)	27.085 (± 37.159)	

Notes:

[49] - PK Population

[50] - PK Population

[51] - PK Population

Statistical analyses

No statistical analyses for this end point

Primary: Apparent volume of distribution during terminal phase (V_z) of pazopanib

End point title	Apparent volume of distribution during terminal phase (V _z) of pazopanib ^[52]
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End point description:

Plasma samples were collected at indicated time points to evaluate V_z. Geometric mean and coefficient of variation were calculated.

End point type	Primary
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End point timeframe:

Pre-dose, 30 min, 1 hour (h), 2h, 4h, 6h, 8h, 10-12 h and 24 h post-dose at Day 1 and pre-dose, 1 h, 2h, 4h, 6h, 8h at Day 15/22 of Cycle 1

Notes:

[52] - 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: There are no statistical data to report.

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[53]	2 ^[54]	2 ^[55]	3 ^[56]
Units: Liter per Square Meter (L/m ²)				
geometric mean (geometric coefficient of variation)	8.461 (± 74.375)	17.317 (± 120.183)	10.116 (± 115.347)	9.75 (± 49.537)

Notes:

- [53] - PK Population
- [54] - PK Population
- [55] - PK Population
- [56] - PK Population

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9 ^[57]	4 ^[58]	3 ^[59]	
Units: Liter per Square Meter (L/m ²)				
geometric mean (geometric coefficient of variation)	7.196 (± 49.151)	7.823 (± 50.35)	21.587 (± 39.075)	

Notes:

- [57] - PK Population
- [58] - PK Population
- [59] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with the indicated Overall Response (OR)

End point title	Number of participants with the indicated Overall Response (OR) ^[60]
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End point description:

Overall tumor response is defined as the number of participants achieving either a confirmed complete or partial tumor response per Response Evaluation Criteria in Solid Tumors (RECIST). RECIST guidelines were used to evaluate the measurability of tumor lesions, to determine target and non-target lesions at Baseline, and to evaluate tumor response or disease progression after study start. Complete Response (CR) is defined as the disappearance of all target and non-target lesions, and Partial Response (PR) is defined as at least a 30% decrease in the sum of the longest diameters (LD) of target lesions, taking as a reference the Baseline sum LD, as assessed by the investigator. Incomplete Response/Stable Disease (IR/SD) is defined as persistence of one or more non-target lesions. Progressive Disease (PD) is defined as appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions.

End point type	Secondary
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End point timeframe:

30 days after last dose of study treatment (maximum of approximately 13 months)

Notes:

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

Justification: There are no statistical data to report.

End point values	Part 2b: Pazopanib 450 mg/m ²	Part 1: Pazopanib Tablet	Part 2: Pazopanib OS	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	10 ^[61]	27 ^[62]	16 ^[63]	
Units: Participants				
Complete Response	0	0	0	
Partial Response	1	1	0	
Stable Disease	4	7	1	
Non-CR/Non-PD	0	0	0	
Progressive Disease	5	3	2	
Not Evaluable	0	16	13	

CR+PR	1	1	0	
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Notes:

[61] - Safety Population

[62] - Safety Population

[63] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with change in circulating biomarkers in peripheral blood

End point title	Number of participants with change in circulating biomarkers in peripheral blood
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End point description:

Circulating endothelial cells (CECs), circulating endothelial precursor cells (CEPs), monocyte counts, and plasma angiogenic factors in peripheral blood were planned to be measured using four-color flow cytometry methods. Data are not available for this outcome measure.

End point type	Secondary
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End point timeframe:

Day 1 and Day 15 of Cycle 1

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[64]	0 ^[65]	0 ^[66]	0 ^[67]
Units: Participants				

Notes:

[64] - Safety Population

[65] - Safety Population

[66] - Safety Population

[67] - Safety Population

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[68]	0 ^[69]	0 ^[70]	
Units: Participants				

Notes:

[68] - Safety Population

[69] - Safety Population

[70] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with change in tumor vascular permeability in response to pazopanib

End point title	Number of participants with change in tumor vascular permeability in response to pazopanib
End point description: Tumor vascular permeability assessment using dynamic contrast enhanced-magnetic resonance imaging (DCE-MRI) scan was planned. Data are not available for this outcome measure.	
End point type	Secondary
End point timeframe: Day 1 and Day 15 of Cycle 1	

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[71]	0 ^[72]	0 ^[73]	0 ^[74]
Units: Participants				

Notes:

[71] - Safety Population

[72] - Safety Population

[73] - Safety Population

[74] - Safety Population

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[75]	0 ^[76]	0 ^[77]	
Units: Participants				

Notes:

[75] - Safety Population

[76] - Safety Population

[77] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants showing vascular endothelial growth factor (VEGF) haplotype/phenotype relationships

End point title	Number of participants showing vascular endothelial growth factor (VEGF) haplotype/phenotype relationships
End point description: Blood samples were planned to be collected at indicated time points for gene expression studies. Data are not available for this outcome measure.	
End point type	Secondary
End point timeframe: Day 1 and Day 15 of Cycle 1	

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[78]	0 ^[79]	0 ^[80]	0 ^[81]
Units: Participants				

Notes:

[78] - Safety Population

[79] - Safety Population

[80] - Safety Population

[81] - Safety Population

End point values	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²	Part 2b: Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[82]	0 ^[83]	0 ^[84]	
Units: Participants				

Notes:

[82] - Safety Population

[83] - Safety Population

[84] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants showing pazopanib concentration-effect relationships with biomarkers and clinical outcomes

End point title	Number of participants showing pazopanib concentration-effect relationships with biomarkers and clinical outcomes
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End point description:

Blood samples were planned to be collected at indicated time points for assessment of pazopanib concentration-effect relationships with biomarkers and clinical outcomes. Data are not available for this outcome measure.

End point type	Secondary
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End point timeframe:

Day 1 and Day 15 of Cycle 1

End point values	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²	Part 1: Pazopanib 600 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[85]	0 ^[86]	0 ^[87]	0 ^[88]
Units: Participants				

Notes:

[85] - Safety Population

[86] - Safety Population

[87] - Safety Population

[88] - Safety Population

End point values	Part 2a:	Part 2a:	Part 2b:	
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	Pazopanib OS 160 mg/m ²	Pazopanib OS 225 mg/m ²	Pazopanib 450 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[89]	0 ^[90]	0 ^[91]	
Units: Participants				

Notes:

[89] - Safety Population

[90] - Safety Population

[91] - Safety Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On-treatment serious adverse events (SAEs) and non-serious adverse events (AEs) were collected from the start of the study treatment until 30 days after the last dose of study treatment.

Adverse event reporting additional description:

SAEs and non-serious AEs were collected in participants of the Safety Population, comprised of all participants who received at least one dose of pazopanib.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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Reporting groups

Reporting group title	Part 1: Pazopanib 275 mg/m ²
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Reporting group description:

In the Phase I part, participants received pazopanib tablets 275 milligrams (mg)/square meter (m²), orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Reporting group title	Part 1: Pazopanib 350 mg/m ²
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Reporting group description:

In the Phase I part, participants received pazopanib tablets 350 mg/m², orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Reporting group title	Part 1: Pazopanib 450 mg/m ²
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Reporting group description:

In the Phase I part, participants received Pazopanib tablets 450 mg/m², orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Reporting group title	Part 1: Pazopanib 600 mg/m ²
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Reporting group description:

In the Phase I part, participants received Pazopanib tablets 600 mg/m², orally, once daily, for a cycle of 28 days. Each participant could receive a maximum of 24 cycles. The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time each day with clear liquids.

Reporting group title	Part 2a: Pazopanib OS 160 mg/m ²
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Reporting group description:

In the Phase 2a part, participants received pazopanib suspension at a dose of 160 mg/m². The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time.

Reporting group title	Part 2a: Pazopanib OS 225 mg/m ²
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Reporting group description:

In the Phase 2a part, participants received pazopanib suspension formulation of 225 mg/m². The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time.

Reporting group title	Part 2b: Pazopanib 450 mg/m ²
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Reporting group description:

In the Phase 2b part, participants received pazopanib tablets of 450 mg/m². The study drug was taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal) at approximately the same time day with clear liquids.

Serious adverse events	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 7 (57.14%)	2 / 6 (33.33%)	3 / 7 (42.86%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Death NOS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fever			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (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
Edema Limbs			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Irregular Menstruation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Dyspnea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Agitation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychosis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Lipase Increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serum Amylase Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight Gain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight Loss			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Cardiac Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (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

Depressed Level Of Consciousness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Nerve Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial Hemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory Impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensory Neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Anemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hemolysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucositis Oral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Periodontal Disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palmar-Plantar Erythrodysesthesia Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (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
Skin And Subcutaneous Tissue Disorders - Other, Specify			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal And Urinary Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	5 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back Pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Wall Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalized Muscle Weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Soft Tissue Necrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Anorexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (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
Hypokalemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (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
Hypoalbuminemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatremia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1: Pazopanib 600 mg/m ²	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)	4 / 12 (33.33%)	2 / 4 (50.00%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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			
Hypertension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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
General disorders and administration site conditions			
Death NOS			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Fever			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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
Edema Limbs			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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	1 / 7 (14.29%)	0 / 12 (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
Reproductive system and breast disorders			
Irregular Menstruation			

subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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			
Dyspnea			
subjects affected / exposed	2 / 7 (28.57%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (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
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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			
Agitation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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			
Lipase Increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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

Serum Amylase Increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight Gain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight Loss			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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			
Cardiac Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed Level Of Consciousness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Nerve Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial Hemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory Impairment			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	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
Nervous System Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensory Neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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			
Anemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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
Hemolysis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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

Gastrointestinal Disorders - Other, Specify			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucositis Oral			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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
Periodontal Disease			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Dry Skin			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palmar-Plantar Erythrodysesthesia Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin And Subcutaneous Tissue Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal And Urinary Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
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			
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Wall Pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalized Muscle Weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Soft Tissue Necrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (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
Pain In Extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal Infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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
Infections And Infestations - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (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
Upper Respiratory Infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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

Hypocalcemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (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
Hyponatremia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2b: Pazopanib 450 mg/m ²		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 10 (50.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor Pain			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death NOS			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fever			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Edema Limbs			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Irregular Menstruation			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnea			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural Effusion			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Confusion			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychosis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Lipase Increased			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Serum Amylase Increased			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alkaline Phosphatase Increased			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight Gain			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Weight Loss			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac Disorders - Other, Specify			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depressed Level Of Consciousness			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Facial Nerve Disorder			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intracranial Hemorrhage			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Memory Impairment			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous System Disorders - Other, Specify			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral Sensory Neuropathy			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Hemolysis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal Disorders - Other, Specify			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Abdominal distension			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Diarrhea			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mucositis Oral			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periodontal Disease			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Palmar-Plantar Erythrodysesthesia			

Syndrome			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Skin And Subcutaneous Tissue Disorders - Other, Specify			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal And Urinary Disorders - Other, Specify			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest Wall Pain			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Generalized Muscle Weakness			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Head Soft Tissue Necrosis			
subjects affected / exposed	0 / 10 (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 / 10 (10.00%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal Infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections And Infestations - Other, Specify			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper Respiratory Infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypocalcemia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Hypokalemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercalcemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoalbuminemia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatremia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part 1: Pazopanib 275 mg/m ²	Part 1: Pazopanib 350 mg/m ²	Part 1: Pazopanib 450 mg/m ²
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	6 / 6 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	3
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 7 (42.86%)	5 / 6 (83.33%)	2 / 7 (28.57%)
occurrences (all)	3	12	3
Hypotension			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hematoma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hot Flashes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	5 / 7 (71.43%)	4 / 6 (66.67%)	5 / 7 (71.43%)
occurrences (all)	7	4	12
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	1	1	4
Edema Limbs			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Gait Disturbance			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Fever			

subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Edema Trunk			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Death NOS			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Edema Face			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Facial Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Immune System Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
Irregular Menstruation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Vaginal Hemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pelvic Floor Muscle Weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal Dryness			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 7 (42.86%)	4 / 6 (66.67%)	3 / 7 (42.86%)
occurrences (all)	5	4	5
Respiratory, Thoracic And Mediastinal Disorders - Other, Specify			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Allergic Rhinitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
Dyspnea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Pharyngolaryngeal Pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Atelectasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Voice Alteration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Nasal Congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural Effusion			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sore Throat			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleuritic Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Depression			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Agitation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Personality Change			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1

Confusion subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Investigations			
White Blood Cell Decreased subjects affected / exposed occurrences (all)	5 / 7 (71.43%) 13	4 / 6 (66.67%) 5	5 / 7 (71.43%) 19
Neutrophil Count Decreased subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 12	4 / 6 (66.67%) 7	4 / 7 (57.14%) 13
Lymphocyte Count Decreased subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	3 / 6 (50.00%) 4	3 / 7 (42.86%) 4
Aspartate Aminotransferase Increased subjects affected / exposed occurrences (all)	5 / 7 (71.43%) 8	2 / 6 (33.33%) 2	5 / 7 (71.43%) 6
Alanine Aminotransferase Increased subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	0 / 6 (0.00%) 0	6 / 7 (85.71%) 8
Platelet Count Decreased subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 4	4 / 6 (66.67%) 4	3 / 7 (42.86%) 4
Alkaline Phosphatase Increased subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	2 / 6 (33.33%) 2	2 / 7 (28.57%) 3
Activated Partial Thromboplastin Time Prolonged subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 4	1 / 6 (16.67%) 1	2 / 7 (28.57%) 2
Investigations - Other, Specify subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 13	1 / 6 (16.67%) 4	1 / 7 (14.29%) 2
Creatinine increased subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 6 (16.67%) 1	4 / 7 (57.14%) 8
Serum Amylase Increased			

subjects affected / exposed	2 / 7 (28.57%)	3 / 6 (50.00%)	2 / 7 (28.57%)
occurrences (all)	8	4	12
Weight Loss			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	2
Lipase Increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Blood Bilirubin Increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	1	4	1
GGT Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight Gain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood antidiuretic hormone abnormal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Cholesterol High			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
INR Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Bruising			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis Radiation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fracture			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Vascular access complication subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Wound Dehiscence subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Cardiac disorders Cardiac Disorders - Other, Specify subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 3	1 / 6 (16.67%) 1	0 / 7 (0.00%) 0
Sinus Bradycardia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	1 / 7 (14.29%) 1
Sinus Tachycardia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 6 (16.67%) 1	0 / 7 (0.00%) 0
Conduction Disorder subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Ventricular Arrhythmia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	3 / 6 (50.00%) 4	5 / 7 (71.43%) 7
Dizziness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	3 / 6 (50.00%) 5	3 / 7 (42.86%) 4
Peripheral Sensory Neuropathy subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	3 / 7 (42.86%) 5
Ataxia			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	2
Abducens Nerve Disorder			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	1	1	3
Cognitive Disturbance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	3
Facial Nerve Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nystagmus			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Seizure			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Tremor			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Depressed Level Of Consciousness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Dysphasia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Glossopharyngeal Nerve Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Memory Impairment			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Nervous System Disorders - Other,			

Specify			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Oculomotor Nerve Disorder			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Trigeminal Nerve Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Extrapyramidal Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglossal Nerve Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
IVth nerve disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyramidal Tract Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vagus Nerve Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	4 / 7 (57.14%)	2 / 6 (33.33%)	5 / 7 (71.43%)
occurrences (all)	5	2	17
Blood And Lymphatic System Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Disseminated Intravascular Coagulation			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hemolysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spleen disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hearing Impaired			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
External Ear Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Ear And Labyrinth Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Ear Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Middle Ear Inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eye disorders			
Blurred Vision			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Eye Disorders - Other, Specify			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Extraocular Muscle Paresis			

subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Optic Nerve Disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Photophobia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Cataract			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dry Eye			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Flashing Lights			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhea			
subjects affected / exposed	6 / 7 (85.71%)	2 / 6 (33.33%)	6 / 7 (85.71%)
occurrences (all)	8	2	8
Vomiting			
subjects affected / exposed	5 / 7 (71.43%)	3 / 6 (50.00%)	4 / 7 (57.14%)
occurrences (all)	6	3	11
Nausea			
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	3 / 7 (42.86%)
occurrences (all)	4	2	7
Abdominal Pain			
subjects affected / exposed	2 / 7 (28.57%)	2 / 6 (33.33%)	3 / 7 (42.86%)
occurrences (all)	2	4	6
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	1	2	3

Gastrointestinal Disorders - Other, Specify			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Mucositis Oral			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
Stomach Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Rectal Hemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Oral Hemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Fecal Incontinence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rectal Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Anal Hemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dental Caries			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Oral Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periodontal Disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	4
Hepatobiliary disorders			
Hepatobiliary Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash Maculo-Papular			
subjects affected / exposed	4 / 7 (57.14%)	1 / 6 (16.67%)	4 / 7 (57.14%)
occurrences (all)	4	1	6
Skin Hypopigmentation			
subjects affected / exposed	2 / 7 (28.57%)	2 / 6 (33.33%)	3 / 7 (42.86%)
occurrences (all)	2	2	4
Skin And Subcutaneous Tissue Disorders - Other, Specify			
subjects affected / exposed	1 / 7 (14.29%)	2 / 6 (33.33%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Alopecia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	4 / 7 (57.14%)
occurrences (all)	1	0	4
Dry Skin			

subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Rash Acneiform			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Palmar-Plantar Erythrodysesthesia Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Skin Hyperpigmentation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photosensitivity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin Ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	4 / 7 (57.14%)
occurrences (all)	8	2	6
Hematuria			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Hemoglobinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal And Urinary Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Urinary Frequency			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
Urinary tract pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Urine Discoloration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cystitis noninfective			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	3 / 7 (42.86%)	4 / 6 (66.67%)	2 / 7 (28.57%)
occurrences (all)	3	5	2
Cushingoid			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	3 / 7 (42.86%)
occurrences (all)	2	1	4
Pain In Extremity			

subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Musculoskeletal And Connective Tissue Disorder - Other, Specify			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Chest Wall Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck Pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Bone Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Buttock Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Generalized Muscle Weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle Weakness Lower Limb			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle Weakness Left-Sided			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Muscle Weakness Trunk subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	1 / 7 (14.29%) 1
Muscle Weakness Upper Limb subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Pelvic Soft Tissue Necrosis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Scoliosis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Trismus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0
Infections and infestations			
Otitis Media subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 6 (33.33%) 2	1 / 7 (14.29%) 1
Upper Respiratory Infection subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 6 (16.67%) 1	1 / 7 (14.29%) 2
Infections And Infestations - Other, Specify subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 6 (16.67%) 1	1 / 7 (14.29%) 1
Conjunctivitis subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	1 / 7 (14.29%) 1
Sinusitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 6 (16.67%) 1	0 / 7 (0.00%) 0
Urinary Tract Infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	1 / 7 (14.29%) 1
Bladder Infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Phlebitis Infective			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hyperglycemia			
subjects affected / exposed	2 / 7 (28.57%)	3 / 6 (50.00%)	4 / 7 (57.14%)
occurrences (all)	5	4	6
Hyponatremia			
subjects affected / exposed	2 / 7 (28.57%)	3 / 6 (50.00%)	3 / 7 (42.86%)
occurrences (all)	2	3	14
Hypoalbuminemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	3 / 7 (42.86%)
occurrences (all)	2	2	6
Hypophosphatemia			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	3 / 7 (42.86%)
occurrences (all)	2	3	6
Anorexia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	1	1	5
Hypoglycemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	3 / 7 (42.86%)
occurrences (all)	4	1	16
Hypercalcemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	3	1	0

Hypocalcemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	9
Hypermagnesemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	4 / 7 (57.14%)
occurrences (all)	0	2	14
Acidosis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Hypomagnesemia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Hyperkalemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Hypernatremia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalemia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	7

Non-serious adverse events	Part 1: Pazopanib 600 mg/m ²	Part 2a: Pazopanib OS 160 mg/m ²	Part 2a: Pazopanib OS 225 mg/m ²
Total subjects affected by non-serious adverse events			

subjects affected / exposed	7 / 7 (100.00%)	12 / 12 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 7 (42.86%)	4 / 12 (33.33%)	3 / 4 (75.00%)
occurrences (all)	8	7	3
Hypotension			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Flushing			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Hematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot Flashes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular Disorders - Other, Specify			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vasculitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 7 (85.71%)	4 / 12 (33.33%)	3 / 4 (75.00%)
occurrences (all)	10	4	3
Pain			

subjects affected / exposed	2 / 7 (28.57%)	3 / 12 (25.00%)	0 / 4 (0.00%)
occurrences (all)	4	5	0
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Edema Limbs			
subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Gait Disturbance			
subjects affected / exposed	2 / 7 (28.57%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	7	0	0
Fever			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Edema Trunk			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Death NOS			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Edema Face			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Facial Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Immune System Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Irregular Menstruation subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Vaginal Hemorrhage subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 12 (8.33%) 1	0 / 4 (0.00%) 0
Pelvic Floor Muscle Weakness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Vaginal Dryness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	4 / 7 (57.14%) 5	2 / 12 (16.67%) 3	1 / 4 (25.00%) 1
Respiratory, Thoracic And Mediastinal Disorders - Other, Specify subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	3 / 12 (25.00%) 4	1 / 4 (25.00%) 1
Epistaxis subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	0 / 12 (0.00%) 0	1 / 4 (25.00%) 1
Allergic Rhinitis subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 4	1 / 12 (8.33%) 2	0 / 4 (0.00%) 0
Dyspnea subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 4	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Pharyngolaryngeal Pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 12 (0.00%) 0	1 / 4 (25.00%) 1
Atelectasis			

subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Voice Alteration			
subjects affected / exposed	2 / 7 (28.57%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hiccups			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nasal Congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural Effusion			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	2 / 7 (28.57%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Sore Throat			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Pleuritic Pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sinus Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1

Insomnia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Personality Change			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
White Blood Cell Decreased			
subjects affected / exposed	3 / 7 (42.86%)	7 / 12 (58.33%)	2 / 4 (50.00%)
occurrences (all)	22	16	4
Neutrophil Count Decreased			
subjects affected / exposed	2 / 7 (28.57%)	3 / 12 (25.00%)	2 / 4 (50.00%)
occurrences (all)	7	4	7
Lymphocyte Count Decreased			
subjects affected / exposed	5 / 7 (71.43%)	6 / 12 (50.00%)	2 / 4 (50.00%)
occurrences (all)	22	15	3
Aspartate Aminotransferase Increased			
subjects affected / exposed	3 / 7 (42.86%)	2 / 12 (16.67%)	3 / 4 (75.00%)
occurrences (all)	4	2	5
Alanine Aminotransferase Increased			
subjects affected / exposed	5 / 7 (71.43%)	5 / 12 (41.67%)	3 / 4 (75.00%)
occurrences (all)	5	8	5
Platelet Count Decreased			
subjects affected / exposed	2 / 7 (28.57%)	4 / 12 (33.33%)	3 / 4 (75.00%)
occurrences (all)	6	5	5
Alkaline Phosphatase Increased			

subjects affected / exposed	3 / 7 (42.86%)	2 / 12 (16.67%)	2 / 4 (50.00%)
occurrences (all)	4	3	3
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	2 / 7 (28.57%)	2 / 12 (16.67%)	1 / 4 (25.00%)
occurrences (all)	6	3	1
Investigations - Other, Specify			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	3 / 4 (75.00%)
occurrences (all)	2	3	25
Creatinine increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	5	3	1
Serum Amylase Increased			
subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	0 / 4 (0.00%)
occurrences (all)	4	2	0
Weight Loss			
subjects affected / exposed	2 / 7 (28.57%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	4	2	1
Lipase Increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood Bilirubin Increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
GGT Increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Weight Gain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cholesterol High			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

INR Increased subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Injury, poisoning and procedural complications			
Bruising subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	1 / 4 (25.00%) 1
Dermatitis Radiation subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 12 (8.33%) 1	0 / 4 (0.00%) 0
Fracture subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Vascular access complication subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Wound Dehiscence subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Cardiac disorders			
Cardiac Disorders - Other, Specify subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	1 / 12 (8.33%) 1	1 / 4 (25.00%) 1
Sinus Bradycardia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 9	1 / 12 (8.33%) 1	0 / 4 (0.00%) 0
Sinus Tachycardia subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 3	0 / 12 (0.00%) 0	1 / 4 (25.00%) 1
Conduction Disorder subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 12 (8.33%) 1	0 / 4 (0.00%) 0
Ventricular Arrhythmia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Nervous system disorders			

Headache			
subjects affected / exposed	5 / 7 (71.43%)	3 / 12 (25.00%)	1 / 4 (25.00%)
occurrences (all)	10	3	3
Dizziness			
subjects affected / exposed	2 / 7 (28.57%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	3	0	1
Peripheral Sensory Neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	2 / 12 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Ataxia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Abducens Nerve Disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cognitive Disturbance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Facial Nerve Disorder			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Nystagmus			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Seizure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Depressed Level Of Consciousness			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Dysphasia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glossopharyngeal Nerve Disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Memory Impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous System Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oculomotor Nerve Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral Motor Neuropathy			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Trigeminal Nerve Disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Extrapyramidal Disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypoglossal Nerve Disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
IVth nerve disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pyramidal Tract Syndrome			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vagus Nerve Disorder			

subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 2	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	5 / 7 (71.43%)	6 / 12 (50.00%)	2 / 4 (50.00%)
occurrences (all)	9	7	4
Blood And Lymphatic System Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disseminated Intravascular Coagulation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hemolysis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Spleen disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hearing Impaired			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
External Ear Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear And Labyrinth Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Middle Ear Inflammation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tinnitus			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Eye disorders			
Blurred Vision			
subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Eye Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Extraocular Muscle Paresis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Optic Nerve Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eye Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flashing Lights			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhea			
subjects affected / exposed	3 / 7 (42.86%)	4 / 12 (33.33%)	1 / 4 (25.00%)
occurrences (all)	5	8	2
Vomiting			

subjects affected / exposed	4 / 7 (57.14%)	4 / 12 (33.33%)	2 / 4 (50.00%)
occurrences (all)	6	5	2
Nausea			
subjects affected / exposed	4 / 7 (57.14%)	4 / 12 (33.33%)	1 / 4 (25.00%)
occurrences (all)	6	5	1
Abdominal Pain			
subjects affected / exposed	2 / 7 (28.57%)	3 / 12 (25.00%)	1 / 4 (25.00%)
occurrences (all)	5	3	1
Constipation			
subjects affected / exposed	3 / 7 (42.86%)	3 / 12 (25.00%)	2 / 4 (50.00%)
occurrences (all)	4	4	2
Gastrointestinal Disorders - Other, Specify			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Mucositis Oral			
subjects affected / exposed	2 / 7 (28.57%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Stomach Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	2 / 4 (50.00%)
occurrences (all)	1	0	2
Rectal Hemorrhage			
subjects affected / exposed	2 / 7 (28.57%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral Hemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Toothache			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Fecal Incontinence subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 12 (0.00%) 0	1 / 4 (25.00%) 1
Gingival Pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Rectal Pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	1 / 4 (25.00%) 1
Anal Hemorrhage subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Dental Caries subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Oral Pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Periodontal Disease subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Hepatobiliary disorders Hepatobiliary Disorders - Other, Specify subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 12 (8.33%) 1	0 / 4 (0.00%) 0
Skin and subcutaneous tissue disorders Rash Maculo-Papular subjects affected / exposed occurrences (all) Skin Hypopigmentation	0 / 7 (0.00%) 0	2 / 12 (16.67%) 3	1 / 4 (25.00%) 1

subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Skin And Subcutaneous Tissue Disorders - Other, Specify			
subjects affected / exposed	2 / 7 (28.57%)	2 / 12 (16.67%)	1 / 4 (25.00%)
occurrences (all)	3	2	2
Alopecia			
subjects affected / exposed	3 / 7 (42.86%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	3	0	1
Dry Skin			
subjects affected / exposed	0 / 7 (0.00%)	4 / 12 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Pruritus			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Rash Acneiform			
subjects affected / exposed	0 / 7 (0.00%)	2 / 12 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Palmar-Plantar Erythrodysesthesia Syndrome			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Skin Hyperpigmentation			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photosensitivity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin Ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Proteinuria			
subjects affected / exposed	4 / 7 (57.14%)	6 / 12 (50.00%)	2 / 4 (50.00%)
occurrences (all)	7	11	5
Hematuria			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Hemoglobinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Renal And Urinary Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Urinary Frequency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine Discoloration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis noninfective			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Urinary Retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	5 / 7 (71.43%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	9	0	2
Cushingoid			

subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Endocrine Disorders - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	4 / 7 (57.14%)	3 / 12 (25.00%)	0 / 4 (0.00%)
occurrences (all)	6	5	0
Pain In Extremity			
subjects affected / exposed	0 / 7 (0.00%)	4 / 12 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	5	3
Arthralgia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Musculoskeletal And Connective Tissue Disorder - Other, Specify			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Chest Wall Pain			
subjects affected / exposed	2 / 7 (28.57%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Joint range of motion decreased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 12 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Myalgia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Neck Pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	2
Bone Pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Buttock Pain			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Generalized Muscle Weakness subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 12 (8.33%) 1	0 / 4 (0.00%) 0
Muscle Weakness Lower Limb subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 12 (8.33%) 1	0 / 4 (0.00%) 0
Muscle Weakness Left-Sided subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 2	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Muscle Weakness Trunk subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Muscle Weakness Upper Limb subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	1 / 4 (25.00%) 1
Pelvic Soft Tissue Necrosis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Scoliosis subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Trismus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	0 / 4 (0.00%) 0
Infections and infestations Otitis Media subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 12 (0.00%) 0	1 / 4 (25.00%) 1
Upper Respiratory Infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 12 (8.33%) 1	0 / 4 (0.00%) 0
Infections And Infestations - Other, Specify			

subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Urinary Tract Infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bladder Infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lip Infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Phlebitis Infective			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycemia			
subjects affected / exposed	3 / 7 (42.86%)	4 / 12 (33.33%)	2 / 4 (50.00%)
occurrences (all)	5	4	3
Hyponatremia			
subjects affected / exposed	1 / 7 (14.29%)	5 / 12 (41.67%)	3 / 4 (75.00%)
occurrences (all)	1	6	4
Hypoalbuminemia			
subjects affected / exposed	2 / 7 (28.57%)	5 / 12 (41.67%)	3 / 4 (75.00%)
occurrences (all)	5	6	7

Hypophosphatemia			
subjects affected / exposed	3 / 7 (42.86%)	4 / 12 (33.33%)	3 / 4 (75.00%)
occurrences (all)	9	4	3
Anorexia			
subjects affected / exposed	2 / 7 (28.57%)	3 / 12 (25.00%)	3 / 4 (75.00%)
occurrences (all)	4	3	3
Hypoglycemia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	2 / 4 (50.00%)
occurrences (all)	3	4	4
Hypercalcemia			
subjects affected / exposed	3 / 7 (42.86%)	2 / 12 (16.67%)	3 / 4 (75.00%)
occurrences (all)	3	2	3
Hypocalcemia			
subjects affected / exposed	2 / 7 (28.57%)	2 / 12 (16.67%)	1 / 4 (25.00%)
occurrences (all)	2	2	1
Hypermagnesemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Acidosis			
subjects affected / exposed	2 / 7 (28.57%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	3	1	2
Hypomagnesemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	15	2	2
Hyperkalemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Hypernatremia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 12 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Hyperuricemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypokalemia			
subjects affected / exposed	2 / 7 (28.57%)	3 / 12 (25.00%)	1 / 4 (25.00%)
occurrences (all)	4	5	1

Non-serious adverse events	Part 2b: Pazopanib 450 mg/m ²		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor Pain			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) - Other, Specify			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 10 (60.00%)		
occurrences (all)	10		
Hypotension			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	14		
Flushing			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Hematoma			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hot Flashes			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Vascular Disorders - Other, Specify			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Vasculitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	9 / 10 (90.00%)		
occurrences (all)	14		
Pain			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	9		
Non-Cardiac Chest Pain			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Edema Limbs			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Gait Disturbance			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Fever			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Edema Trunk			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		
Chills			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Death NOS			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Edema Face</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Facial Pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 10 (0.00%)</p> <p>0</p> <p>0 / 10 (0.00%)</p> <p>0</p> <p>1 / 10 (10.00%)</p> <p>1</p>		
<p>Immune system disorders</p> <p>Immune System Disorders - Other, Specify</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 10 (0.00%)</p> <p>0</p>		
<p>Reproductive system and breast disorders</p> <p>Irregular Menstruation</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pelvic pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vaginal Hemorrhage</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pelvic Floor Muscle Weakness</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vaginal Dryness</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 10 (20.00%)</p> <p>2</p> <p>1 / 10 (10.00%)</p> <p>1</p> <p>0 / 10 (0.00%)</p> <p>0</p> <p>1 / 10 (10.00%)</p> <p>1</p> <p>0 / 10 (0.00%)</p> <p>0</p>		
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Respiratory, Thoracic And Mediastinal Disorders - Other, Specify</p>	<p>3 / 10 (30.00%)</p> <p>5</p>		

subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	6		
Epistaxis			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	10		
Allergic Rhinitis			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		
Dyspnea			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Pharyngolaryngeal Pain			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	5		
Atelectasis			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Voice Alteration			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hiccups			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Nasal Congestion			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Pleural Effusion			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Pneumothorax			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sore Throat			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Hypoxia			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pleuritic Pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sinus Disorder			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	5		
Insomnia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Depression			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Agitation			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Personality Change			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Confusion			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Investigations			
White Blood Cell Decreased			
subjects affected / exposed	8 / 10 (80.00%)		
occurrences (all)	39		
Neutrophil Count Decreased			

subjects affected / exposed	8 / 10 (80.00%)		
occurrences (all)	25		
Lymphocyte Count Decreased			
subjects affected / exposed	8 / 10 (80.00%)		
occurrences (all)	29		
Aspartate Aminotransferase Increased			
subjects affected / exposed	6 / 10 (60.00%)		
occurrences (all)	14		
Alanine Aminotransferase Increased			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	14		
Platelet Count Decreased			
subjects affected / exposed	6 / 10 (60.00%)		
occurrences (all)	13		
Alkaline Phosphatase Increased			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Investigations - Other, Specify			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	5		
Creatinine increased			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	4		
Serum Amylase Increased			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Weight Loss			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	9		
Lipase Increased			

subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	20		
Blood Bilirubin Increased			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
GGT Increased			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Weight Gain			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	3		
Blood antidiuretic hormone abnormal			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Cholesterol High			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
INR Increased			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Bruising			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Dermatitis Radiation			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Fracture			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Vascular access complication			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Wound Dehiscence			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Cardiac disorders			
Cardiac Disorders - Other, Specify subjects affected / exposed occurrences (all)	4 / 10 (40.00%) 5		
Sinus Bradycardia subjects affected / exposed occurrences (all)	5 / 10 (50.00%) 10		
Sinus Tachycardia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Conduction Disorder subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Ventricular Arrhythmia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	7 / 10 (70.00%) 20		
Dizziness subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 3		
Peripheral Sensory Neuropathy subjects affected / exposed occurrences (all)	4 / 10 (40.00%) 4		
Ataxia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Abducens Nerve Disorder subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Cognitive Disturbance			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Facial Nerve Disorder			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Nystagmus			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Seizure			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Depressed Level Of Consciousness			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dysphasia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Glossopharyngeal Nerve Disorder			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Memory Impairment			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Nervous System Disorders - Other, Specify			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Oculomotor Nerve Disorder			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		

Peripheral Motor Neuropathy subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Trigeminal Nerve Disorder subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Extrapyramidal Disorder subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Hypoglossal Nerve Disorder subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
IVth nerve disorder subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Pyramidal Tract Syndrome subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Vagus Nerve Disorder subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Blood and lymphatic system disorders Anemia subjects affected / exposed occurrences (all)	8 / 10 (80.00%) 14		
Blood And Lymphatic System Disorders - Other, Specify subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Disseminated Intravascular Coagulation subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Hemolysis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Spleen disorder			

subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Ear and labyrinth disorders			
Hearing Impaired			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
External Ear Pain			
subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Ear And Labyrinth Disorders - Other, Specify			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Ear Pain			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Middle Ear Inflammation			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Tinnitus			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Eye disorders			
Blurred Vision			
subjects affected / exposed occurrences (all)	4 / 10 (40.00%) 4		
Eye Disorders - Other, Specify			
subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Extraocular Muscle Paresis			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Optic Nerve Disorder			
subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Photophobia			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Cataract			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dry Eye			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Eye Pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Flashing Lights			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Gastrointestinal disorders			
Diarrhea			
subjects affected / exposed	7 / 10 (70.00%)		
occurrences (all)	19		
Vomiting			
subjects affected / exposed	6 / 10 (60.00%)		
occurrences (all)	20		
Nausea			
subjects affected / exposed	7 / 10 (70.00%)		
occurrences (all)	26		
Abdominal Pain			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	7		
Constipation			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	11		
Gastrointestinal Disorders - Other, Specify			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	4		
Mucositis Oral			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Stomach Pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Rectal Hemorrhage			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Flatulence			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Oral Hemorrhage			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Fecal Incontinence			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Gingival Pain			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Rectal Pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Anal Hemorrhage			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Dental Caries			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Oral Pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Periodontal Disease			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Hepatobiliary Disorders - Other, Specify			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Rash Maculo-Papular			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	5		
Skin Hypopigmentation			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	6		
Skin And Subcutaneous Tissue Disorders - Other, Specify			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	7		
Alopecia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Dry Skin			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		
Pruritus			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Rash Acneiform			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Palmar-Plantar Erythrodysesthesia Syndrome			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Skin Hyperpigmentation			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Photosensitivity			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	2		
Skin Ulceration			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	6 / 10 (60.00%)		
occurrences (all)	16		
Hematuria			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	5		
Hemoglobinuria			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	4		
Urinary Incontinence			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Renal And Urinary Disorders - Other, Specify			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Urinary Frequency			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Urinary tract pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Urine Discoloration			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Cystitis noninfective			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Urinary Retention			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	13		
Cushingoid			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Endocrine Disorders - Other, Specify			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	8		
Pain In Extremity			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	10		
Arthralgia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	4		
Musculoskeletal And Connective Tissue Disorder - Other, Specify			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Chest Wall Pain			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Joint range of motion decreased			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Neck Pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Bone Pain			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Buttock Pain			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Generalized Muscle Weakness			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Muscle Weakness Lower Limb			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Muscle Weakness Left-Sided			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Muscle Weakness Trunk			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Muscle Weakness Upper Limb			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pelvic Soft Tissue Necrosis			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Scoliosis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Trismus			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Infections and infestations			
Otitis Media			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Upper Respiratory Infection			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Infections And Infestations - Other, Specify			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Urinary Tract Infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Bladder Infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Lip Infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pharyngitis			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Phlebitis Infective			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Skin Infection			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hyperglycemia			
subjects affected / exposed	7 / 10 (70.00%)		
occurrences (all)	18		
Hyponatremia			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	5		
Hypoalbuminemia			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	22		
Hypophosphatemia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	3		
Anorexia			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	11		
Hypoglycemia			
subjects affected / exposed	5 / 10 (50.00%)		
occurrences (all)	8		
Hypercalcemia			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	7		
Hypocalcemia			
subjects affected / exposed	4 / 10 (40.00%)		
occurrences (all)	18		
Hypermagnesemia			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	5		

Acidosis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Hypomagnesemia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	12		
Hyperkalemia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Hypernatremia			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dehydration			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	4		
Hypertriglyceridemia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Hyperuricemia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Obesity			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Hypokalemia			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported