



Clinical trial results:

A Phase 1/2a Study of BMS-986178 Administered Alone or in Combination with Nivolumab and/or Ipilimumab in Subjects with Advanced Solid Tumors

Summary

EudraCT number	2015-004816-39
Trial protocol	ES NL IT
Global end of trial date	02 November 2020

Results information

Result version number	v1 (current)
This version publication date	18 November 2021
First version publication date	18 November 2021

Trial information

Trial identification

Sponsor protocol code	CA012-004
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 September 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	02 November 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to determine the safety, tolerability, dose-limiting toxicities (DLTs), and maximum tolerated dose (MTD)/recommended Phase 2 dose (RP2D) of BMS-986178 administered alone or in combination with nivolumab and/or ipilimumab in subjects with advanced solid tumors.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 June 2016
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: 68
Country: Number of subjects enrolled	Canada: 27
Country: Number of subjects enrolled	Israel: 2
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Netherlands: 17
Country: Number of subjects enrolled	Spain: 50
Worldwide total number of subjects	166
EEA total number of subjects	69

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	100
From 65 to 84 years	66
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

165 participants were randomized and treated in Parts 1-8. 1 Participant was randomized and treated in Part 9 Cohort 1. Parts 2B, 2D, 2E, 3B, 3C, and Part 9 Cohort 2 did not enroll any participants.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: BMS 20 mg Q2W

Arm description:

Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 20mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.

Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

20 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Arm title	Part 1: BMS 40 mg Q2W
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Arm description:

Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 40mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.

Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

40 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Arm title	Part 1: BMS 80 mg Q2W
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Arm description:

Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 80mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.

Arm type	Experimental
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Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
80 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Arm title	Part 1: BMS 160 mg Q2W
Arm description:	
Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 160mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
160 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Arm title	Part 1: BMS 320 mg Q2W
Arm description:	
Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 320mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
320 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Arm title	Part 2 BMS 20 mg + Nivo 240 mg Q2W
Arm description:	
Dosing of BMS-986178 20mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
20 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
240 mg - Administered as a flat dose	
Arm title	Part 2: BMS 40 mg + Nivo 240 mg Q2W
Arm description:	
Dosing of BMS-986178 40mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
240 mg - Administered as a flat dose	
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
40 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Arm title	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Arm description:	
Dosing of BMS-986178 80mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
240 mg - Administered as a flat dose	
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
80 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Arm title	Part 2: BMS 160 mg + Nivo 240 mg Q2W
Arm description:	
Dosing of BMS-986178 160mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Arm type	Experimental

Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

160 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

240 mg - Administered as a flat dose

Arm title	Part 2: BMS 320 mg + Nivo 240 mg Q2W
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Arm description:

Dosing of BMS-986178 320mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

240 mg - Administered as a flat dose

Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

320 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Arm title	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W
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Arm description:

Each treatment cycle will be 3 weeks in length. BMS-986178 20mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.

Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

20 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
1 mg/kg	
Arm title	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Arm description:	
Each treatment cycle will be 3 weeks in length. BMS-986178 40mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.	
Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
40 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
1 mg/kg	
Arm title	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W
Arm description:	
Each treatment cycle will be 3 weeks in length. BMS-986178 80mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.	
Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
80 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
1 mg/kg	
Arm title	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W

Arm description:

Each treatment cycle will be 3 weeks in length. BMS-986178 160mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.

Arm type	Experimental
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

1 mg/kg

Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

160 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Arm title	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W
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Arm description:

Each treatment cycle will be 3 weeks in length. BMS-986178 320mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.

Arm type	Experimental
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

1 mg/kg

Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

320 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Arm title	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
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Arm description:

Participants with bladder cancer receive BMS-986178 (80 mg) and Nivolumab administered at a flat dose of 240 mg. Each treatment cycle will be 2 weeks in length and study drugs will be administered every 2 weeks starting on Day 1 of each cycle for up to 12 cycles.

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:	
240 mg - Administered as a flat dose	
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
80 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Arm title	Part 4: BMS 80 mg + Nivo 480mg Q4W
Arm description:	
Combination arm of BMS-986178 (80 mg) with nivolumab (480 mg) to be administered every 4 weeks (q4w).	
Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
80 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
480 mg - Administered as a flat dose	
Arm title	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W
Arm description:	
Combination arm of BMS-986178 (80 mg) with Ipilimumab 3 mg/kg administered every 3 weeks (q3w) for 4 doses, followed by monotherapy with BMS-986178 (maintenance therapy).	
Arm type	Experimental
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
3 mg/kg	
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
80 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	

Arm title	Part 6A:BMS40mg+Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480mgQ4W
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Arm description:

Participants with renal cell carcinoma (RCC) receive BMS-986178 (40mg) administered at a flat dose in combination with nivolumab (240 mg) and ipilimumab (1 mg/kg) every 3 weeks (q3w) during Cycles 1 to 4, followed by maintenance therapy (Cycle 5 and beyond) in which BMS-986178 (40 mg) and nivolumab (480 mg) will be administered every 4 weeks (q4w). Study drugs will be administered accordingly starting on Day 1 of each cycle.

Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

40 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

1 mg/kg

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

240 mg - Administered as a flat dose

Arm title	Part6B:BMS40mg+Nivo240 mg+Ipi1mg/kgQ3W/BMS 40mg+Nivo480 mgQ4W
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Arm description:

Participants with renal cell carcinoma (RCC) receive BMS-986178 (40mg) administered combination with nivolumab (240 mg) and ipilimumab (1 mg/kg) every 3 weeks (q3w) during Cycles 1 to 4 followed by maintenance therapy (Cycle 5 and beyond) in which BMS-986178 and nivolumab (480 mg) will be administered every 4 weeks (q4w). Study drugs will be administered accordingly starting on Day 1 of each cycle.

Arm type	Experimental
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

1 mg/kg

Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

40 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be

infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Arm title	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W
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Arm description:

BMS-986178 will be administered at a flat dose of 40 mg (q2w) in combination with nivolumab (240 mg; q2w) and ipilimumab (1 mg/kg; q6w) for four 6-week cycles. Study drugs will be administered accordingly starting on Day 1 of each cycle. If participants continue for additional cycles, past cycle 4, all study drugs (BMS-986178/nivolumab/ipilimumab) will continue for all cycles.

Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

40 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

1 mg/kg

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

240 mg - Administered as a flat dose

Arm title	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W
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Arm description:

Participants with non-small cell lung cancer (NSCLC) receive BMS-986178 (40 mg) in combination with nivolumab 240 mg every 2 weeks (q2w) and ipilimumab 1 mg/kg every 6 weeks (q6w) for four, 6-week cycles. Study drugs will be administered accordingly starting on Day 1 of each cycle.

Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

40 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
240 mg - Administered as a flat dose	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
240 mg - Administered as a flat dose	
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
1 mg/kg	
Arm title	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W
Arm description:	
BMS-986178 (20 mg) will be administered as a flat dose every 12 weeks (q12w) in combination with nivolumab flat dose (480 mg) every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length starting on Day 1 of each cycle. There will be up to 9 cycles, to allow for 24 months of treatment. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab and BMS-986178.	
Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
20 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
480 mg - Administered as a flat dose	
Investigational medicinal product name	Tetanus vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intradermal use
Dosage and administration details:	
Tdap preferred, Td or equivalent administered first on Cycle 1 Day 1 prior to administration of other study treatments	
Arm title	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W

Arm description:

BMS-986178 (40 mg) will be administered as a flat dose every 12 weeks (q12w) in combination with nivolumab flat dose (480 mg) every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length starting on Day 1 of each cycle. There will be up to 9 cycles, to allow for 24 months of treatment. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab and BMS-986178.

Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

40 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

480 mg - Administered as a flat dose

Investigational medicinal product name	Tetanus vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intradermal use

Dosage and administration details:

Tdap preferred, Td or equivalent administered first on Cycle 1 Day 1 prior to administration of other study treatments

Arm title	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W
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Arm description:

BMS-986178 (80 mg) will be administered as a flat dose every 12 weeks (q12w) in combination with nivolumab flat dose (480 mg) every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length starting on Day 1 of each cycle. There will be up to 9 cycles, to allow for 24 months of treatment. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab and BMS-986178.

Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

80 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Investigational medicinal product name	Tetanus vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intradermal use

Dosage and administration details:

Tdap preferred, Td or equivalent administered first on Cycle 1 Day 1 prior to administration of other study treatments

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

480 mg - Administered as a flat dose

Arm title	Part 8: Cohort 4- Nivo 480 mg Q4W
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Arm description:

Nivolumab monotherapy will be administered as a flat dose of 480 mg every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length and will be dosed for up to 9 cycles, 24 months of dosing. Treatment will be given on Day 1, Day 29 and 57 of each cycle. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab monotherapy.

Arm type	Experimental
Investigational medicinal product name	Tetanus vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intradermal use

Dosage and administration details:

Tdap preferred, Td or equivalent administered first on Cycle 1 Day 1 prior to administration of other study treatments

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

480 mg - Administered as a flat dose

Arm title	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine
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Arm description:

Cohort 1: Cyclophosphamide 300 mg/m² was administered 3 days prior to C1D1. DPV-001 1 mg was given on C1D1 intranodal then intradermal on C1D8, C1D15, C2D1, C2D15, C3D1, C4D1, C5D1, C6D1, C9D1 and C12D1. Nivolumab 240 mg was administered on C1D15 followed by nivolumab 480 mg was Q4W on day 1 of cycles 2-26. BMS-986178 40 mg infusion was administered on day 1 of cycles 1-6, 9, and 12. Each treatment cycle is 4 weeks and there are up to 26 cycles.

Arm type	Experimental
Investigational medicinal product name	BMS-986178
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

40 mg - The administration of the entire bag or syringe (if syringe pump is used) contents should be infused over approximately 30 minutes (including a flush up to 20 mL to completely flush the infusion line), through an IV infusion set

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection

Routes of administration	Intravenous use
Dosage and administration details:	
480 mg - Administered as a flat dose	
Investigational medicinal product name	DPV-001 (UbiLT3 and UbiLT6)
Investigational medicinal product code	
Other name	DRibbles Vaccine
Pharmaceutical forms	Injection
Routes of administration	Other use

Dosage and administration details:

0.5 mL UbiLT3 into 1 lymph node and 0.5 mL of UbiLT6 into another lymph node - administered intranodal under ultrasound guidance.

Investigational medicinal product name	DPV-001 (UbiLT3 and UbiLT6)
Investigational medicinal product code	
Other name	DRibbles Vaccine
Pharmaceutical forms	Injection
Routes of administration	Intradermal use

Dosage and administration details:

1 mg - can alternate between either UbiLT3 or UbiLT6

Number of subjects in period 1	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W
Started	4	4	4
Completed	3	4	4
Not completed	1	0	0
Adverse event, serious fatal	1	-	-
Participant withdrew consent	-	-	-
Other reasons	-	-	-
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 1: BMS 160 mg Q2W	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W
Started	4	4	7
Completed	3	3	4
Not completed	1	1	3
Adverse event, serious fatal	1	-	-
Participant withdrew consent	-	-	2
Other reasons	-	1	1
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W	Part 2: BMS 160 mg + Nivo 240 mg Q2W
Started	8	12	8
Completed	8	10	7
Not completed	0	2	1

Adverse event, serious fatal	-	2	-
Participant withdrew consent	-	-	-
Other reasons	-	-	1
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Started	8	4	10
Completed	8	3	6
Not completed	0	1	4
Adverse event, serious fatal	-	-	4
Participant withdrew consent	-	-	-
Other reasons	-	1	-
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W
Started	7	8	6
Completed	5	6	5
Not completed	2	2	1
Adverse event, serious fatal	2	2	-
Participant withdrew consent	-	-	1
Other reasons	-	-	-
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W
Started	18	12	6
Completed	15	10	2
Not completed	3	2	4
Adverse event, serious fatal	2	2	2
Participant withdrew consent	-	-	2
Other reasons	-	-	-
Lost to follow-up	1	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 6A: BMS40mg+Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480mgQ 4W	Part6B:BMS40mg+Nivo240 mg+Ipi1mg/kgQ3W/ BMS 40 mg+Nivo480 mgQ4W	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W
Started	7	1	6

Completed	5	1	4
Not completed	2	0	2
Adverse event, serious fatal	1	-	-
Participant withdrew consent	1	-	2
Other reasons	-	-	-
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Started	9	2	2
Completed	8	2	1
Not completed	1	0	1
Adverse event, serious fatal	-	-	-
Participant withdrew consent	-	-	-
Other reasons	1	-	1
Lost to follow-up	-	-	-
Disease Progression	-	-	-

Number of subjects in period 1	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine
Started	2	2	1
Completed	1	1	0
Not completed	1	1	1
Adverse event, serious fatal	-	-	-
Participant withdrew consent	-	-	-
Other reasons	1	1	-
Lost to follow-up	-	-	-
Disease Progression	-	-	1

Baseline characteristics

Reporting groups

Reporting group title	Part 1: BMS 20 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 20mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 1: BMS 40 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 40mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 1: BMS 80 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 80mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 1: BMS 160 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 160mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 1: BMS 320 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 320mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 2 BMS 20 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 20mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 2: BMS 40 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 40mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 80mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 2: BMS 160 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 160mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 2: BMS 320 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 320mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W
Reporting group description: Each treatment cycle will be 3 weeks in length. BMS-986178 20mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.	
Reporting group title	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Reporting group description: Each treatment cycle will be 3 weeks in length. BMS-986178 40mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.	
Reporting group title	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W

Reporting group description:

Each treatment cycle will be 3 weeks in length. BMS-986178 80mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.

Reporting group title	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W
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Reporting group description:

Each treatment cycle will be 3 weeks in length. BMS-986178 160mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.

Reporting group title	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W
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Reporting group description:

Each treatment cycle will be 3 weeks in length. BMS-986178 320mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.

Reporting group title	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
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Reporting group description:

Participants with bladder cancer receive BMS-986178 (80 mg) and Nivolumab administered at a flat dose of 240 mg. Each treatment cycle will be 2 weeks in length and study drugs will be administered every 2 weeks starting on Day 1 of each cycle for up to 12 cycles.

Reporting group title	Part 4: BMS 80 mg + Nivo 480mg Q4W
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Reporting group description:

Combination arm of BMS-986178 (80 mg) with nivolumab (480 mg) to be administered every 4 weeks (q4w).

Reporting group title	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W
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Reporting group description:

Combination arm of BMS-986178 (80 mg) with Ipilimumab 3 mg/kg administered every 3 weeks (q3w) for 4 doses, followed by monotherapy with BMS-986178 (maintenance therapy).

Reporting group title	Part 6A: BMS40mg+Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480mgQ4W
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Reporting group description:

Participants with renal cell carcinoma (RCC) receive BMS-986178 (40mg) administered at a flat dose in combination with nivolumab (240 mg) and ipilimumab (1 mg/kg) every 3 weeks (q3w) during Cycles 1 to 4, followed by maintenance therapy (Cycle 5 and beyond) in which BMS-986178 (40 mg) and nivolumab (480 mg) will be administered every 4 weeks (q4w). Study drugs will be administered accordingly starting on Day 1 of each cycle.

Reporting group title	Part6B: BMS40mg+Nivo240 mg+Ipi1mg/kgQ3W/BMS 40 mg+Nivo480 mgQ4W
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Reporting group description:

Participants with renal cell carcinoma (RCC) receive BMS-986178 (40mg) administered combination with nivolumab (240 mg) and ipilimumab (1 mg/kg) every 3 weeks (q3w) during Cycles 1 to 4 followed by maintenance therapy (Cycle 5 and beyond) in which BMS-986178 and nivolumab (480 mg) will be administered every 4 weeks (q4w). Study drugs will be administered accordingly starting on Day 1 of each cycle.

Reporting group title	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W
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Reporting group description:

BMS-986178 will be administered at a flat dose of 40 mg (q2w) in combination with nivolumab (240 mg; q2w) and ipilimumab (1 mg/kg; q6w) for four 6-week cycles. Study drugs will be administered accordingly starting on Day 1 of each cycle. If participants continue for additional cycles, past cycle 4, all study drugs (BMS-986178/nivolumab/ipilimumab) will continue for all cycles.

Reporting group title	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W
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Reporting group description:

Participants with non-small cell lung cancer (NSCLC) receive BMS-986178 (40 mg) in combination with nivolumab 240 mg every 2 weeks (q2w) and ipilimumab 1 mg/kg every 6 weeks (q6w) for four, 6-week cycles. Study drugs will be administered accordingly starting on Day 1 of each cycle.

Reporting group title	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W
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Reporting group description:

BMS-986178 (20 mg) will be administered as a flat dose every 12 weeks (q12w) in combination with nivolumab flat dose (480 mg) every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length

starting on Day 1 of each cycle. There will be up to 9 cycles, to allow for 24 months of treatment. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab and BMS-986178.

Reporting group title	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
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Reporting group description:

BMS-986178 (40 mg) will be administered as a flat dose every 12 weeks (q12w) in combination with nivolumab flat dose (480 mg) every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length starting on Day 1 of each cycle. There will be up to 9 cycles, to allow for 24 months of treatment. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab and BMS-986178.

Reporting group title	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W
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Reporting group description:

BMS-986178 (80 mg) will be administered as a flat dose every 12 weeks (q12w) in combination with nivolumab flat dose (480 mg) every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length starting on Day 1 of each cycle. There will be up to 9 cycles, to allow for 24 months of treatment. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab and BMS-986178.

Reporting group title	Part 8: Cohort 4- Nivo 480 mg Q4W
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Reporting group description:

Nivolumab monotherapy will be administered as a flat dose of 480 mg every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length and will be dosed for up to 9 cycles, 24 months of dosing. Treatment will be given on Day 1, Day 29 and 57 of each cycle. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab monotherapy.

Reporting group title	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine
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Reporting group description:

Cohort 1: Cyclophosphamide 300 mg/m² was administered 3 days prior to C1D1. DPV-001 1 mg was given on C1D1 intranodal then intradermal on C1D8, C1D15, C2D1, C2D15, C3D1, C4D1, C5D1, C6D1, C9D1 and C12D1. Nivolumab 240 mg was administered on C1D15 followed by nivolumab 480 mg was Q4W on day 1 of cycles 2-26. BMS-986178 40 mg infusion was administered on day 1 of cycles 1-6, 9, and 12. Each treatment cycle is 4 weeks and there are up to 26 cycles.

Reporting group values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W
Number of subjects	4	4	4
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	4	1	2
>=65 years	0	3	2
Age continuous Units: years			
arithmetic mean	43.5	68.5	53.5
standard deviation	± 16.8	± 10.8	± 18.9
Sex: Female, Male Units: Participants			
Female	1	1	3
Male	3	3	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	2	3	4
More than one race	0	0	0
Unknown or Not Reported	1	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	3	4	4
Unknown or Not Reported	0	0	0

Reporting group values	Part 1: BMS 160 mg Q2W	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W
Number of subjects	4	4	7
Age Categorical			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	1	3	5
>=65 years	3	1	2
Age continuous			
Units: years			
arithmetic mean	60.0	55.0	58.4
standard deviation	± 16.2	± 14.0	± 6.8
Sex: Female, Male			
Units: Participants			
Female	1	1	3
Male	3	3	4
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	4	3	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	3	2	6
Unknown or Not Reported	1	2	0

Reporting group values	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W	Part 2: BMS 160 mg + Nivo 240 mg Q2W
Number of subjects	8	12	8
Age Categorical			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	3	10	5
>=65 years	5	2	3

Age continuous Units: years arithmetic mean standard deviation	66.8 ± 10.2	55.0 ± 10.3	59.1 ± 12.3
Sex: Female, Male Units: Participants			
Female	6	3	6
Male	2	9	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	8	12	8
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	6	5	3
Unknown or Not Reported	2	6	5

Reporting group values	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Number of subjects	8	4	10
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	5	3	7
>=65 years	3	1	3
Age continuous Units: years arithmetic mean standard deviation	61.1 ± 7.3	56.5 ± 13.2	59.5 ± 8.7
Sex: Female, Male Units: Participants			
Female	2	3	5
Male	6	1	5
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	8	4	8
More than one race	0	0	0
Unknown or Not Reported	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			

Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	2	7
Unknown or Not Reported	5	2	3

Reporting group values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W
Number of subjects	7	8	6
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	4	7	4
>=65 years	3	1	2
Age continuous Units: years			
arithmetic mean	60.3	47.4	56.7
standard deviation	± 12.7	± 13.7	± 10.8
Sex: Female, Male Units: Participants			
Female	4	7	2
Male	3	1	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	7	7	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	0	0
Not Hispanic or Latino	4	4	5
Unknown or Not Reported	1	4	1

Reporting group values	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W
Number of subjects	18	12	6
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	8	8	5
>=65 years	10	4	1
Age continuous Units: years			
arithmetic mean	65.8	56.8	54.3
standard deviation	± 7.7	± 11.1	± 15.6
Sex: Female, Male Units: Participants			
Female	1	8	3
Male	17	4	3

Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	18	11	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	6	5	3
Unknown or Not Reported	12	7	3

Reporting group values	Part 6A: BMS40mg+Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480mgQ4W	Part6B: BMS40mg+Nivo240 mg+Ipi1mg/kgQ3W/ BMS 40 mg+Nivo480 mgQ4W	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W
Number of subjects	7	1	6
Age Categorical			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	7	0	2
>=65 years	0	1	4
Age continuous			
Units: years			
arithmetic mean	52.0	71.0	65.3
standard deviation	± 12.2	± 99999	± 7.9
Sex: Female, Male			
Units: Participants			
Female	2	0	2
Male	5	1	4
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	7	1	5
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	0	1	4
Unknown or Not Reported	6	0	2

Reporting group values	Part 7B: BMS 40mg Q2W + Nivo 240 mg	Part 8: Cohort 1- BMS 20 mg Q12W +	Part 8: Cohort 2- BMS 40 mg Q12W +
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	Q2W + Ipi 1 mg/kg Q6W	Nivo 480 mg Q4W	Nivo 480 mg Q4W
Number of subjects	9	2	2
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	2	2	1
>=65 years	7	0	1
Age continuous Units: years			
arithmetic mean	69.7	62.0	66.5
standard deviation	± 8.3	± 2.8	± 7.8
Sex: Female, Male Units: Participants			
Female	0	0	1
Male	9	2	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	8	2	2
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	1	2
Unknown or Not Reported	6	1	0

Reporting group values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine
Number of subjects	2	2	1
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	0	0	1
>=65 years	2	2	0
Age continuous Units: years			
arithmetic mean	71.0	75.0	51.0
standard deviation	± 5.7	± 5.7	± 99999
Sex: Female, Male Units: Participants			
Female	1	0	1
Male	1	2	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0

Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	2	2	1
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	1	1	1
Unknown or Not Reported	1	1	0

Reporting group values	Total		
Number of subjects	166		
Age Categorical			
Units: Participants			
<=18 years	0		
Between 18 and 65 years	100		
>=65 years	66		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: Participants			
Female	67		
Male	99		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	1		
Asian	4		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	4		
White	155		
More than one race	0		
Unknown or Not Reported	2		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	6		
Not Hispanic or Latino	89		
Unknown or Not Reported	71		

End points

End points reporting groups

Reporting group title	Part 1: BMS 20 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 20mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 1: BMS 40 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 40mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 1: BMS 80 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 80mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 1: BMS 160 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 160mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 1: BMS 320 mg Q2W
Reporting group description: Part 1A is BMS-986178 monotherapy dose escalation. Dosing of BMS-986178 320mg will begin on Day 1 of each cycle and will be administered every 2 week (q2w) for up to 12 cycles.	
Reporting group title	Part 2 BMS 20 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 20mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 2: BMS 40 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 40mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 80mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 2: BMS 160 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 160mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 2: BMS 320 mg + Nivo 240 mg Q2W
Reporting group description: Dosing of BMS-986178 320mg and Nivolumab flat dose of 240 mg will be administered every 2 weeks (q2w) starting on Day 1 of each cycle for up to 12 cycles.	
Reporting group title	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W
Reporting group description: Each treatment cycle will be 3 weeks in length. BMS-986178 20mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.	
Reporting group title	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Reporting group description: Each treatment cycle will be 3 weeks in length. BMS-986178 40mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.	
Reporting group title	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W

Reporting group description:

Each treatment cycle will be 3 weeks in length. BMS-986178 80mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.

Reporting group title	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W
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Reporting group description:

Each treatment cycle will be 3 weeks in length. BMS-986178 160mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.

Reporting group title	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W
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Reporting group description:

Each treatment cycle will be 3 weeks in length. BMS-986178 320mg will be administered q3w starting on Cycle 1 Day 1, up to and including 8 cycles. Ipilimumab will be administered at a dose of 1 mg/kg q3w starting on Day 1 for 4 cycles. Only BMS-986178 will be administered in the last 4 cycles.

Reporting group title	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
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Reporting group description:

Participants with bladder cancer receive BMS-986178 (80 mg) and Nivolumab administered at a flat dose of 240 mg. Each treatment cycle will be 2 weeks in length and study drugs will be administered every 2 weeks starting on Day 1 of each cycle for up to 12 cycles.

Reporting group title	Part 4: BMS 80 mg + Nivo 480mg Q4W
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Reporting group description:

Combination arm of BMS-986178 (80 mg) with nivolumab (480 mg) to be administered every 4 weeks (q4w).

Reporting group title	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W
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Reporting group description:

Combination arm of BMS-986178 (80 mg) with Ipilimumab 3 mg/kg administered every 3 weeks (q3w) for 4 doses, followed by monotherapy with BMS-986178 (maintenance therapy).

Reporting group title	Part 6A: BMS40mg+Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480mgQ4W
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Reporting group description:

Participants with renal cell carcinoma (RCC) receive BMS-986178 (40mg) administered at a flat dose in combination with nivolumab (240 mg) and ipilimumab (1 mg/kg) every 3 weeks (q3w) during Cycles 1 to 4, followed by maintenance therapy (Cycle 5 and beyond) in which BMS-986178 (40 mg) and nivolumab (480 mg) will be administered every 4 weeks (q4w). Study drugs will be administered accordingly starting on Day 1 of each cycle.

Reporting group title	Part6B: BMS40mg+Nivo240 mg+Ipi1mg/kgQ3W/BMS 40 mg+Nivo480 mgQ4W
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Reporting group description:

Participants with renal cell carcinoma (RCC) receive BMS-986178 (40mg) administered combination with nivolumab (240 mg) and ipilimumab (1 mg/kg) every 3 weeks (q3w) during Cycles 1 to 4 followed by maintenance therapy (Cycle 5 and beyond) in which BMS-986178 and nivolumab (480 mg) will be administered every 4 weeks (q4w). Study drugs will be administered accordingly starting on Day 1 of each cycle.

Reporting group title	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W
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Reporting group description:

BMS-986178 will be administered at a flat dose of 40 mg (q2w) in combination with nivolumab (240 mg; q2w) and ipilimumab (1 mg/kg; q6w) for four 6-week cycles. Study drugs will be administered accordingly starting on Day 1 of each cycle. If participants continue for additional cycles, past cycle 4, all study drugs (BMS-986178/nivolumab/ipilimumab) will continue for all cycles.

Reporting group title	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W
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Reporting group description:

Participants with non-small cell lung cancer (NSCLC) receive BMS-986178 (40 mg) in combination with nivolumab 240 mg every 2 weeks (q2w) and ipilimumab 1 mg/kg every 6 weeks (q6w) for four, 6-week cycles. Study drugs will be administered accordingly starting on Day 1 of each cycle.

Reporting group title	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W
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Reporting group description:

BMS-986178 (20 mg) will be administered as a flat dose every 12 weeks (q12w) in combination with nivolumab flat dose (480 mg) every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length

starting on Day 1 of each cycle. There will be up to 9 cycles, to allow for 24 months of treatment. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab and BMS-986178.

Reporting group title	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
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Reporting group description:

BMS-986178 (40 mg) will be administered as a flat dose every 12 weeks (q12w) in combination with nivolumab flat dose (480 mg) every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length starting on Day 1 of each cycle. There will be up to 9 cycles, to allow for 24 months of treatment. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab and BMS-986178.

Reporting group title	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W
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Reporting group description:

BMS-986178 (80 mg) will be administered as a flat dose every 12 weeks (q12w) in combination with nivolumab flat dose (480 mg) every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length starting on Day 1 of each cycle. There will be up to 9 cycles, to allow for 24 months of treatment. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab and BMS-986178.

Reporting group title	Part 8: Cohort 4- Nivo 480 mg Q4W
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Reporting group description:

Nivolumab monotherapy will be administered as a flat dose of 480 mg every 4 weeks (q4w). Each treatment cycle will be 12 weeks in length and will be dosed for up to 9 cycles, 24 months of dosing. Treatment will be given on Day 1, Day 29 and 57 of each cycle. A tetanus vaccine (Tdap preferred, Td or equivalent after discussion with the medical monitor) will be administered first on Cycle 1 Day 1 prior to administration of nivolumab monotherapy.

Reporting group title	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine
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Reporting group description:

Cohort 1: Cyclophosphamide 300 mg/m² was administered 3 days prior to C1D1. DPV-001 1 mg was given on C1D1 intranodal then intradermal on C1D8, C1D15, C2D1, C2D15, C3D1, C4D1, C5D1, C6D1, C9D1 and C12D1. Nivolumab 240 mg was administered on C1D15 followed by nivolumab 480 mg was Q4W on day 1 of cycles 2-26. BMS-986178 40 mg infusion was administered on day 1 of cycles 1-6, 9, and 12. Each treatment cycle is 4 weeks and there are up to 26 cycles.

Primary: The number of Participants Experiencing Adverse Events (AEs)

End point title	The number of Participants Experiencing Adverse Events
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End point description:

The number of participants experiencing adverse events (AEs) to assess the overall safety and tolerability of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab in participants with advanced solid tumors. An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment.

End point type	Primary
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End point timeframe:

From first dose to 100 days after last dose (up to approximately 2.5 years)

Notes:

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

Justification: Only summary statistics were planned for these endpoints

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Participants	4	4	4	3

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Participants	4	7	8	12

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Participants	7	8	4	10

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Participants	7	8	6	18

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W	Part 6B: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Participants	12	6	6	1

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Participants	6	9	2	2

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	1	
Units: Participants	2	2	1	

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants Experiencing Serious Adverse Events (SAEs)

End point title	The Number of Participants Experiencing Serious Adverse Events (SAEs) ^[2]
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End point description:

The number of participants experiencing serious adverse events (SAEs) to assess the overall safety and tolerability of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab in participants with advanced solid tumors. A SAE is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, and/or is an important medical event.

End point type	Primary
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End point timeframe:

From first dose to 100 days after last dose (up to approximately 2.5 years)

Notes:

[2] - 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: Only summary statistics were planned for these endpoints

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Participants	3	4	2	3

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Participants	3	3	6	7

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Participants	4	5	2	6

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Participants	6	5	2	11

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W	Part 6B: BMS 40 mg + Nivo 240 mg + Ipi 1mg/kg Q3W/BMS 40 mg + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Participants	7	4	4	1

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Participants	6	5	0	1

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	1	
Units: Participants	1	1	1	

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants with Clinical Laboratory Test Abnormalities (Hematology)

End point title	The Number of Participants with Clinical Laboratory Test Abnormalities (Hematology) ^[3]
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End point description:

The number of participants with clinical laboratory test abnormalities to assess the overall safety and tolerability of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab in participants with advanced solid tumors. Baseline is defined as the last non-missing measurement prior to the first dosing date and time

End point type	Primary
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End point timeframe:

From baseline to 100 days after last dose (up to approximately 2.5 years)

Notes:

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

Justification: Only summary statistics were planned for these endpoints

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Participants				
HEMOGLOBIN GRADE 1	2	0	4	1
HEMOGLOBIN GRADE 2	1	2	0	2
HEMOGLOBIN GRADE 3	1	1	0	1
PLATELET COUNT GRADE 1	1	1	1	1
PLATELET COUNT GRADE 2	0	0	0	0
PLATELET COUNT GRADE 3	0	0	0	0
LEUKOCYTES GRADE 1	1	1	2	0
LEUKOCYTES GRADE 2	0	0	0	0
LEUKOCYTES GRADE 3	0	0	0	0
LEUKOCYTES GRADE 4	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 1	1	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 2	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 3	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 4	0	0	0	0

End point values	Part 1: BMS	Part 2 BMS 20	Part 2: BMS 40	Part 2: BMS 80
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	320 mg Q2W	mg + Nivo 240 mg Q2W	mg + Nivo 240 mg Q2W	mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Participants				
HEMOGLOBIN GRADE 1	2	1	4	3
HEMOGLOBIN GRADE 2	1	4	2	5
HEMOGLOBIN GRADE 3	0	1	1	1
PLATELET COUNT GRADE 1	0	1	2	1
PLATELET COUNT GRADE 2	0	1	0	0
PLATELET COUNT GRADE 3	0	1	0	0
LEUKOCYTES GRADE 1	0	0	2	1
LEUKOCYTES GRADE 2	0	1	0	0
LEUKOCYTES GRADE 3	0	0	0	0
LEUKOCYTES GRADE 4	0	0	1	1
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 1	0	1	3	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 2	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 3	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 4	0	0	1	1

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Participants				
HEMOGLOBIN GRADE 1	3	6	3	4
HEMOGLOBIN GRADE 2	2	0	1	6
HEMOGLOBIN GRADE 3	2	1	0	0
PLATELET COUNT GRADE 1	1	0	0	1
PLATELET COUNT GRADE 2	0	0	0	0
PLATELET COUNT GRADE 3	0	0	0	0
LEUKOCYTES GRADE 1	2	1	0	1
LEUKOCYTES GRADE 2	1	0	0	1
LEUKOCYTES GRADE 3	0	0	0	0
LEUKOCYTES GRADE 4	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 1	2	0	0	1
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 2	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 3	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 4	0	0	0	0

End point values	Part 3: BMS 80	Part 3: BMS	Part 3: BMS	Part 2C: BMS
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	mg + Ipi 1 mg/kg Q3W	160 mg + Ipi 1 mg/kg Q3W	320 mg + Ipi 1 mg/kg Q3W	80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Participants				
HEMOGLOBIN GRADE 1	2	5	1	9
HEMOGLOBIN GRADE 2	3	1	4	6
HEMOGLOBIN GRADE 3	1	2	1	3
PLATELET COUNT GRADE 1	2	1	2	4
PLATELET COUNT GRADE 2	0	0	0	0
PLATELET COUNT GRADE 3	0	0	0	0
LEUKOCYTES GRADE 1	1	3	2	2
LEUKOCYTES GRADE 2	1	0	0	0
LEUKOCYTES GRADE 3	1	0	1	0
LEUKOCYTES GRADE 4	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 1	0	0	0	2
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 2	1	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 3	1	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 4	0	0	1	0

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/B MS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Participants				
HEMOGLOBIN GRADE 1	4	1	3	1
HEMOGLOBIN GRADE 2	5	2	2	0
HEMOGLOBIN GRADE 3	1	2	0	0
PLATELET COUNT GRADE 1	3	1	1	0
PLATELET COUNT GRADE 2	0	0	1	0
PLATELET COUNT GRADE 3	0	0	0	0
LEUKOCYTES GRADE 1	1	0	0	0
LEUKOCYTES GRADE 2	0	0	1	0
LEUKOCYTES GRADE 3	1	0	0	0
LEUKOCYTES GRADE 4	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 1	0	0	1	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 2	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 3	1	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 4	0	0	0	0

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Participants				
HEMOGLOBIN GRADE 1	2	7	1	1
HEMOGLOBIN GRADE 2	2	2	1	0
HEMOGLOBIN GRADE 3	1	0	0	1
PLATELET COUNT GRADE 1	1	2	0	0
PLATELET COUNT GRADE 2	0	0	0	1
PLATELET COUNT GRADE 3	0	0	0	0
LEUKOCYTES GRADE 1	1	1	0	0
LEUKOCYTES GRADE 2	0	2	0	1
LEUKOCYTES GRADE 3	0	0	0	0
LEUKOCYTES GRADE 4	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 1	0	1	0	1
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 2	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 3	0	1	0	0
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 4	0	0	0	0

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	1	
Units: Participants				
HEMOGLOBIN GRADE 1	1	1	1	
HEMOGLOBIN GRADE 2	1	0	0	
HEMOGLOBIN GRADE 3	0	1	0	
PLATELET COUNT GRADE 1	0	1	0	
PLATELET COUNT GRADE 2	0	0	0	
PLATELET COUNT GRADE 3	0	0	0	
LEUKOCYTES GRADE 1	0	1	0	
LEUKOCYTES GRADE 2	0	0	0	
LEUKOCYTES GRADE 3	0	0	0	
LEUKOCYTES GRADE 4	0	0	0	
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 1	0	0	0	
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 2	0	0	0	

ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 3	0	0	0	
ABSOLUTE NEUTROPHIL COUNT DRV. GRADE 4	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants with Clinical Laboratory Test Abnormalities (LIVER AND KIDNEY FUNCTION)

End point title	The Number of Participants with Clinical Laboratory Test Abnormalities (LIVER AND KIDNEY FUNCTION) ^[4]
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End point description:

The number of participants with clinical laboratory test abnormalities to assess the overall safety and tolerability of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab in participants with advanced solid tumors. Baseline is defined as the last non-missing measurement prior to the first dosing date and time

End point type	Primary
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End point timeframe:

From baseline to 100 days after last dose (up to approximately 2.5 years)

Notes:

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

Justification: Only summary statistics were planned for these endpoints

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Participants				
ALKALINE PHOSPHATASE GRADE 1	2	2	2	1
ALKALINE PHOSPHATASE GRADE 2	1	1	1	2
ALKALINE PHOSPHATASE GRADE 3	0	0	0	0
ASPARTATE AMINOTRANSFERASE GRADE 1	2	3	1	1
ASPARTATE AMINOTRANSFERASE GRADE 2	0	0	1	1
ASPARTATE AMINOTRANSFERASE GRADE 3	0	0	0	1
ASPARTATE AMINOTRANSFERASE GRADE 4	1	0	0	1
ALANINE AMINOTRANSFERASE GRADE 1	1	3	2	2
ALANINE AMINOTRANSFERASE GRADE 2	1	0	0	1
ALANINE AMINOTRANSFERASE GRADE 3	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 4	0	0	0	1
BILIRUBIN, TOTAL GRADE 1	0	0	0	0
BILIRUBIN, TOTAL GRADE 2	0	0	0	2
BILIRUBIN, TOTAL GRADE 3	1	1	1	0
BILIRUBIN, TOTAL GRADE 4	0	0	0	0
CREATININE GRADE 1	2	1	2	1
CREATININE GRADE 2	0	1	0	1
CREATININE GRADE 3	0	0	0	0

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Participants				
ALKALINE PHOSPHATASE GRADE 1	3	5	2	5
ALKALINE PHOSPHATASE GRADE 2	0	1	1	0
ALKALINE PHOSPHATASE GRADE 3	0	0	2	2
ASPARTATE AMINOTRANSFERASE GRADE 1	1	3	4	2
ASPARTATE AMINOTRANSFERASE GRADE 2	0	0	0	0
ASPARTATE AMINOTRANSFERASE GRADE 3	0	0	2	1
ASPARTATE AMINOTRANSFERASE GRADE 4	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 1	0	2	4	1
ALANINE AMINOTRANSFERASE GRADE 2	0	0	1	1
ALANINE AMINOTRANSFERASE GRADE 3	0	0	1	0
ALANINE AMINOTRANSFERASE GRADE 4	0	0	0	0
BILIRUBIN, TOTAL GRADE 1	0	0	1	1
BILIRUBIN, TOTAL GRADE 2	0	0	1	0
BILIRUBIN, TOTAL GRADE 3	0	0	1	1
BILIRUBIN, TOTAL GRADE 4	0	0	1	0
CREATININE GRADE 1	0	0	3	6
CREATININE GRADE 2	1	0	0	0
CREATININE GRADE 3	0	0	0	1

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Participants				
ALKALINE PHOSPHATASE GRADE 1	6	4	2	3
ALKALINE PHOSPHATASE GRADE 2	0	0	1	2
ALKALINE PHOSPHATASE GRADE 3	1	0	0	0
ASPARTATE AMINOTRANSFERASE GRADE 1	1	2	0	4
ASPARTATE AMINOTRANSFERASE GRADE 2	1	0	0	1
ASPARTATE AMINOTRANSFERASE GRADE 3	1	0	2	0
ASPARTATE AMINOTRANSFERASE GRADE 4	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 1	2	0	1	4
ALANINE AMINOTRANSFERASE GRADE 2	0	0	1	0
ALANINE AMINOTRANSFERASE GRADE 3	0	0	1	0

ALANINE AMINOTRANSFERASE GRADE 4	0	0	0	0
BILIRUBIN, TOTAL GRADE 1	0	0	1	1
BILIRUBIN, TOTAL GRADE 2	0	0	0	0
BILIRUBIN, TOTAL GRADE 3	0	0	0	1
BILIRUBIN, TOTAL GRADE 4	0	0	0	0
CREATININE GRADE 1	1	1	0	1
CREATININE GRADE 2	0	0	0	0
CREATININE GRADE 3	0	0	0	0

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Participants				
ALKALINE PHOSPHATASE GRADE 1	3	4	0	7
ALKALINE PHOSPHATASE GRADE 2	0	1	1	3
ALKALINE PHOSPHATASE GRADE 3	1	0	1	2
ASPARTATE AMINOTRANSFERASE GRADE 1	2	2	2	10
ASPARTATE AMINOTRANSFERASE GRADE 2	0	0	2	0
ASPARTATE AMINOTRANSFERASE GRADE 3	0	0	0	0
ASPARTATE AMINOTRANSFERASE GRADE 4	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 1	1	1	2	7
ALANINE AMINOTRANSFERASE GRADE 2	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 3	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 4	0	0	0	0
BILIRUBIN, TOTAL GRADE 1	0	0	0	2
BILIRUBIN, TOTAL GRADE 2	1	0	1	0
BILIRUBIN, TOTAL GRADE 3	0	0	0	0
BILIRUBIN, TOTAL GRADE 4	0	0	0	0
CREATININE GRADE 1	1	3	2	7
CREATININE GRADE 2	1	0	0	3
CREATININE GRADE 3	0	1	0	2

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Participants				
ALKALINE PHOSPHATASE GRADE 1	6	2	1	0

ALKALINE PHOSPHATASE GRADE 2	1	0	1	1
ALKALINE PHOSPHATASE GRADE 3	0	1	0	0
ASPARTATE AMINOTRANSFERASE GRADE 1	5	4	3	0
ASPARTATE AMINOTRANSFERASE GRADE 2	0	1	0	0
ASPARTATE AMINOTRANSFERASE GRADE 3	0	0	1	0
ASPARTATE AMINOTRANSFERASE GRADE 4	0	0	0	1
ALANINE AMINOTRANSFERASE GRADE 1	4	3	1	0
ALANINE AMINOTRANSFERASE GRADE 2	0	0	1	0
ALANINE AMINOTRANSFERASE GRADE 3	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 4	0	0	0	1
BILIRUBIN, TOTAL GRADE 1	0	1	0	0
BILIRUBIN, TOTAL GRADE 2	0	0	0	0
BILIRUBIN, TOTAL GRADE 3	0	0	0	1
BILIRUBIN, TOTAL GRADE 4	0	0	0	0
CREATININE GRADE 1	0	1	2	1
CREATININE GRADE 2	2	0	0	0
CREATININE GRADE 3	0	1	0	0

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Participants				
ALKALINE PHOSPHATASE GRADE 1	3	2	1	0
ALKALINE PHOSPHATASE GRADE 2	1	2	0	1
ALKALINE PHOSPHATASE GRADE 3	0	0	0	0
ASPARTATE AMINOTRANSFERASE GRADE 1	5	2	0	1
ASPARTATE AMINOTRANSFERASE GRADE 2	0	0	0	0
ASPARTATE AMINOTRANSFERASE GRADE 3	0	0	0	0
ASPARTATE AMINOTRANSFERASE GRADE 4	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 1	3	3	0	1
ALANINE AMINOTRANSFERASE GRADE 2	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 3	0	0	0	0
ALANINE AMINOTRANSFERASE GRADE 4	0	0	0	0
BILIRUBIN, TOTAL GRADE 1	0	0	0	0
BILIRUBIN, TOTAL GRADE 2	0	0	0	0
BILIRUBIN, TOTAL GRADE 3	0	0	0	0
BILIRUBIN, TOTAL GRADE 4	0	0	0	0
CREATININE GRADE 1	2	3	1	1
CREATININE GRADE 2	0	2	0	0
CREATININE GRADE 3	0	0	0	0

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	1	
Units: Participants				
ALKALINE PHOSPHATASE GRADE 1	0	0	1	
ALKALINE PHOSPHATASE GRADE 2	0	0	1	
ALKALINE PHOSPHATASE GRADE 3	0	1	0	
ASPARTATE AMINOTRANSFERASE GRADE 1	1	0	1	
ASPARTATE AMINOTRANSFERASE GRADE 2	0	0	1	
ASPARTATE AMINOTRANSFERASE GRADE 3	0	0	0	
ASPARTATE AMINOTRANSFERASE GRADE 4	0	0	0	
ALANINE AMINOTRANSFERASE GRADE 1	0	0	1	
ALANINE AMINOTRANSFERASE GRADE 2	0	0	0	
ALANINE AMINOTRANSFERASE GRADE 3	0	0	0	
ALANINE AMINOTRANSFERASE GRADE 4	0	0	0	
BILIRUBIN, TOTAL GRADE 1	0	0	0	
BILIRUBIN, TOTAL GRADE 2	0	1	1	
BILIRUBIN, TOTAL GRADE 3	0	0	0	
BILIRUBIN, TOTAL GRADE 4	0	0	0	
CREATININE GRADE 1	1	1	0	
CREATININE GRADE 2	0	0	0	
CREATININE GRADE 3	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants with Clinical Laboratory Test Abnormalities (OTHER CHEMISTRY TESTING)

End point title	The Number of Participants with Clinical Laboratory Test Abnormalities (OTHER CHEMISTRY TESTING) ^[5]
End point description:	
The number of participants with clinical laboratory test abnormalities to assess the overall safety and tolerability of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab in participants with advanced solid tumors. Baseline is defined as the last non-missing measurement prior to the first dosing date and time.	
End point type	Primary
End point timeframe:	
From baseline to 100 days after last dose (up to approximately 2.5 years)	

Notes:

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

Justification: Only summary statistics were planned for these endpoints

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Participants				
SODIUM, SERUM GRADE 1	4	3	2	2
SODIUM, SERUM GRADE 2	0	0	0	0
SODIUM, SERUM GRADE 3	0	0	1	0
POTASSIUM, SERUM GRADE 1	0	3	0	2
POTASSIUM, SERUM GRADE 2	0	0	0	0
POTASSIUM, SERUM GRADE 3	0	0	0	1
POTASSIUM, SERUM GRADE 4	0	0	0	0
CALCIUM, TOTAL GRADE 1	0	3	1	1
CALCIUM, TOTAL GRADE 2	1	0	2	0
CALCIUM, TOTAL GRADE 3	0	0	0	1
MAGNESIUM, SERUM GRADE 1	1	1	0	2
MAGNESIUM, SERUM GRADE 2	0	0	0	0
MAGNESIUM, SERUM GRADE 3	0	0	0	0
GLUCOSE, FASTING SERUM GRADE 1	1	3	0	3
GLUCOSE, FASTING SERUM GRADE 2	0	0	1	0
GLUCOSE, FASTING SERUM GRADE 3	1	0	1	0
ALBUMIN GRADE 1	2	2	1	2
ALBUMIN GRADE 2	1	2	2	1
ALBUMIN GRADE 3	0	0	0	1
AMYLASE, TOTAL GRADE 1	1	0	0	0
AMYLASE, TOTAL GRADE 2	0	1	0	0
AMYLASE, TOTAL GRADE 3	0	0	2	1
AMYLASE, TOTAL GRADE 4	0	0	0	0
LIPASE, TOTAL GRADE 1	0	0	0	0
LIPASE, TOTAL GRADE 2	1	0	0	1
LIPASE, TOTAL GRADE 3	1	1	0	1
LIPASE, TOTAL GRADE 4	0	0	0	0

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Participants				
SODIUM, SERUM GRADE 1	1	2	6	5
SODIUM, SERUM GRADE 2	0	0	0	0
SODIUM, SERUM GRADE 3	1	0	0	1
POTASSIUM, SERUM GRADE 1	0	1	4	3
POTASSIUM, SERUM GRADE 2	0	0	0	0
POTASSIUM, SERUM GRADE 3	1	0	1	0

POTASSIUM, SERUM GRADE 4	0	0	0	1
CALCIUM, TOTAL GRADE 1	1	3	5	4
CALCIUM, TOTAL GRADE 2	0	0	1	3
CALCIUM, TOTAL GRADE 3	0	0	0	0
MAGNESIUM, SERUM GRADE 1	2	0	1	3
MAGNESIUM, SERUM GRADE 2	0	1	2	0
MAGNESIUM, SERUM GRADE 3	0	0	0	0
GLUCOSE, FASTING SERUM GRADE 1	1	4	4	2
GLUCOSE, FASTING SERUM GRADE 2	1	0	2	1
GLUCOSE, FASTING SERUM GRADE 3	1	1	0	1
ALBUMIN GRADE 1	1	2	0	4
ALBUMIN GRADE 2	1	3	5	3
ALBUMIN GRADE 3	0	0	0	0
AMYLASE, TOTAL GRADE 1	1	1	0	3
AMYLASE, TOTAL GRADE 2	0	0	1	0
AMYLASE, TOTAL GRADE 3	0	0	0	0
AMYLASE, TOTAL GRADE 4	0	0	1	0
LIPASE, TOTAL GRADE 1	0	0	1	1
LIPASE, TOTAL GRADE 2	0	0	0	1
LIPASE, TOTAL GRADE 3	0	0	0	2
LIPASE, TOTAL GRADE 4	0	0	1	0

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Participants				
SODIUM, SERUM GRADE 1	2	2	2	2
SODIUM, SERUM GRADE 2	0	0	0	0
SODIUM, SERUM GRADE 3	0	0	1	0
POTASSIUM, SERUM GRADE 1	2	2	0	2
POTASSIUM, SERUM GRADE 2	0	0	0	0
POTASSIUM, SERUM GRADE 3	1	1	0	0
POTASSIUM, SERUM GRADE 4	0	0	0	0
CALCIUM, TOTAL GRADE 1	2	4	2	4
CALCIUM, TOTAL GRADE 2	0	0	0	0
CALCIUM, TOTAL GRADE 3	0	0	0	0
MAGNESIUM, SERUM GRADE 1	4	1	2	4
MAGNESIUM, SERUM GRADE 2	0	2	0	0
MAGNESIUM, SERUM GRADE 3	0	0	0	0
GLUCOSE, FASTING SERUM GRADE 1	2	0	2	6
GLUCOSE, FASTING SERUM GRADE 2	0	1	0	1
GLUCOSE, FASTING SERUM GRADE 3	0	0	0	0
ALBUMIN GRADE 1	1	3	1	2
ALBUMIN GRADE 2	3	0	2	4
ALBUMIN GRADE 3	0	0	0	0
AMYLASE, TOTAL GRADE 1	1	0	0	1
AMYLASE, TOTAL GRADE 2	1	0	1	1
AMYLASE, TOTAL GRADE 3	0	0	0	0

AMYLASE, TOTAL GRADE 4	0	0	0	0
LIPASE, TOTAL GRADE 1	1	0	0	1
LIPASE, TOTAL GRADE 2	1	0	0	0
LIPASE, TOTAL GRADE 3	0	1	0	1
LIPASE, TOTAL GRADE 4	0	1	0	0

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Participants				
SODIUM, SERUM GRADE 1	2	2	2	4
SODIUM, SERUM GRADE 2	0	0	0	0
SODIUM, SERUM GRADE 3	0	2	0	2
POTASSIUM, SERUM GRADE 1	3	2	2	8
POTASSIUM, SERUM GRADE 2	0	0	0	3
POTASSIUM, SERUM GRADE 3	0	1	0	1
POTASSIUM, SERUM GRADE 4	0	0	0	1
CALCIUM, TOTAL GRADE 1	3	0	2	9
CALCIUM, TOTAL GRADE 2	0	1	0	1
CALCIUM, TOTAL GRADE 3	0	1	0	1
MAGNESIUM, SERUM GRADE 1	0	0	2	6
MAGNESIUM, SERUM GRADE 2	1	0	0	1
MAGNESIUM, SERUM GRADE 3	0	1	0	0
GLUCOSE, FASTING SERUM GRADE 1	5	2	2	2
GLUCOSE, FASTING SERUM GRADE 2	1	0	0	1
GLUCOSE, FASTING SERUM GRADE 3	0	0	0	0
ALBUMIN GRADE 1	5	2	1	3
ALBUMIN GRADE 2	1	2	3	5
ALBUMIN GRADE 3	0	0	0	0
AMYLASE, TOTAL GRADE 1	0	0	0	2
AMYLASE, TOTAL GRADE 2	1	1	0	2
AMYLASE, TOTAL GRADE 3	0	0	0	1
AMYLASE, TOTAL GRADE 4	0	0	0	0
LIPASE, TOTAL GRADE 1	0	0	1	2
LIPASE, TOTAL GRADE 2	0	1	0	1
LIPASE, TOTAL GRADE 3	0	0	0	2
LIPASE, TOTAL GRADE 4	0	0	0	2

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W	Part 6B: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Participants				
SODIUM, SERUM GRADE 1	3	1	0	0
SODIUM, SERUM GRADE 2	0	0	0	0
SODIUM, SERUM GRADE 3	0	2	1	0
POTASSIUM, SERUM GRADE 1	3	0	1	0
POTASSIUM, SERUM GRADE 2	1	0	1	0
POTASSIUM, SERUM GRADE 3	0	1	0	0
POTASSIUM, SERUM GRADE 4	0	0	0	0
CALCIUM, TOTAL GRADE 1	4	1	4	0
CALCIUM, TOTAL GRADE 2	2	1	0	0
CALCIUM, TOTAL GRADE 3	0	0	0	0
MAGNESIUM, SERUM GRADE 1	2	2	0	0
MAGNESIUM, SERUM GRADE 2	2	0	0	0
MAGNESIUM, SERUM GRADE 3	0	0	0	0
GLUCOSE, FASTING SERUM GRADE 1	99999	99999	0	99999
GLUCOSE, FASTING SERUM GRADE 2	99999	99999	0	99999
GLUCOSE, FASTING SERUM GRADE 3	99999	99999	0	99999
ALBUMIN GRADE 1	4	2	0	0
ALBUMIN GRADE 2	2	2	2	1
ALBUMIN GRADE 3	0	0	0	0
AMYLASE, TOTAL GRADE 1	2	1	1	0
AMYLASE, TOTAL GRADE 2	0	0	0	0
AMYLASE, TOTAL GRADE 3	0	0	0	0
AMYLASE, TOTAL GRADE 4	1	0	0	0
LIPASE, TOTAL GRADE 1	1	1	1	1
LIPASE, TOTAL GRADE 2	0	0	0	0
LIPASE, TOTAL GRADE 3	1	2	2	0
LIPASE, TOTAL GRADE 4	1	0	1	0

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Participants				
SODIUM, SERUM GRADE 1	4	1	0	1
SODIUM, SERUM GRADE 2	0	0	0	0
SODIUM, SERUM GRADE 3	0	0	0	0
POTASSIUM, SERUM GRADE 1	2	2	1	1
POTASSIUM, SERUM GRADE 2	0	0	0	0
POTASSIUM, SERUM GRADE 3	1	0	0	0
POTASSIUM, SERUM GRADE 4	0	0	0	0
CALCIUM, TOTAL GRADE 1	1	5	1	0
CALCIUM, TOTAL GRADE 2	1	0	1	1
CALCIUM, TOTAL GRADE 3	0	0	0	0
MAGNESIUM, SERUM GRADE 1	3	1	0	0

MAGNESIUM, SERUM GRADE 2	0	0	0	0
MAGNESIUM, SERUM GRADE 3	0	0	0	0
GLUCOSE, FASTING SERUM GRADE 1	0	0	99999	99999
GLUCOSE, FASTING SERUM GRADE 2	1	0	99999	99999
GLUCOSE, FASTING SERUM GRADE 3	0	0	99999	99999
ALBUMIN GRADE 1	1	2	1	0
ALBUMIN GRADE 2	3	4	0	0
ALBUMIN GRADE 3	0	0	0	1
AMYLASE, TOTAL GRADE 1	0	1	0	0
AMYLASE, TOTAL GRADE 2	1	0	0	0
AMYLASE, TOTAL GRADE 3	0	0	0	0
AMYLASE, TOTAL GRADE 4	0	0	0	0
LIPASE, TOTAL GRADE 1	1	2	0	0
LIPASE, TOTAL GRADE 2	0	0	0	0
LIPASE, TOTAL GRADE 3	1	2	0	0
LIPASE, TOTAL GRADE 4	0	0	0	0

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	1	
Units: Participants				
SODIUM, SERUM GRADE 1	0	1	1	
SODIUM, SERUM GRADE 2	0	0	0	
SODIUM, SERUM GRADE 3	1	0	1	
POTASSIUM, SERUM GRADE 1	0	0	0	
POTASSIUM, SERUM GRADE 2	0	0	0	
POTASSIUM, SERUM GRADE 3	0	0	0	
POTASSIUM, SERUM GRADE 4	0	0	0	
CALCIUM, TOTAL GRADE 1	0	0	0	
CALCIUM, TOTAL GRADE 2	0	0	0	
CALCIUM, TOTAL GRADE 3	0	0	0	
MAGNESIUM, SERUM GRADE 1	0	2	0	
MAGNESIUM, SERUM GRADE 2	0	0	0	
MAGNESIUM, SERUM GRADE 3	0	0	0	
GLUCOSE, FASTING SERUM GRADE 1	99999	99999	0	
GLUCOSE, FASTING SERUM GRADE 2	99999	99999	0	
GLUCOSE, FASTING SERUM GRADE 3	99999	99999	0	
ALBUMIN GRADE 1	2	1	0	
ALBUMIN GRADE 2	0	1	1	
ALBUMIN GRADE 3	0	0	0	
AMYLASE, TOTAL GRADE 1	0	0	0	
AMYLASE, TOTAL GRADE 2	0	0	0	
AMYLASE, TOTAL GRADE 3	0	0	0	
AMYLASE, TOTAL GRADE 4	0	1	0	
LIPASE, TOTAL GRADE 1	1	0	0	
LIPASE, TOTAL GRADE 2	0	0	0	

LIPASE, TOTAL GRADE 3	0	0	0	
LIPASE, TOTAL GRADE 4	0	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: The number of Participants Experiencing Dose-Limiting Toxicities (DLTs)

End point title	The number of Participants Experiencing Dose-Limiting Toxicities (DLTs) ^[6]
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End point description:

The number of participants experiencing dose-limiting toxicities (DLTs) to assess the overall safety and tolerability of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab in participants with advanced solid tumors. DLTs are defined based on the incidence, severity, and duration of adverse events (AEs) for which no clear alternative cause is identified. An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment.

End point type	Primary
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End point timeframe:

From first dose to 28 days after first dose

Notes:

[6] - 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: Only summary statistics were planned for these endpoints

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Participants	0	0	0	0

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Participants	0	0	0	0

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Participants	1	0	0	0

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Participants	0	0	0	0

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W	Part 6B: BMS 40 mg + Nivo 240 mg + Ipi 1mg/kg Q3W/BMS 40 mg + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Participants	1	1	0	0

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Participants	0	0	0	1

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	1	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation

End point title	The Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation ^[7]
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End point description:

The number of participants experiencing adverse events (AEs) leading to discontinuation of study drug to assess the overall safety and tolerability of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab in participants with advanced solid tumors. An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment.

End point type	Primary
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End point timeframe:

From first dose to 100 days after last dose (up to approximately 2.5 years)

Notes:

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

Justification: Only summary statistics were planned for these endpoints

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Participants	0	0	0	0

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Participants	0	0	0	0

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Participants	1	0	0	2

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Participants	0	2	0	0

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Participants	2	0	2	0

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Participants	0	1	0	0

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	1	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participant Deaths

End point title	The Number of Participant Deaths ^[8]
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End point description:

The number of deaths in each arm to assess the overall safety and tolerability of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab in participants with advanced solid tumors.

End point type	Primary
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End point timeframe:

From first dose to study completion (up to approximately 5 years)

Notes:

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

Justification: Only summary statistics were planned for these endpoints

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Participants	4	4	3	4

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Participants	4	3	7	11

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Participants	6	6	4	9

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Participants	7	8	2	16

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W	Part 6B: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Participants	11	3	3	0

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Participants	5	4	2	2

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	1	
Units: Participants	1	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)
End point description:	
The total number of participants whose best overall response (BOR) is either a complete response (CR) or partial response (PR) Baseline is defined as the last non-missing measurement prior to the first dosing date and time.	
End point type	Secondary
End point timeframe:	
From baseline up to approximately 2.5 years	

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Participants	0	0	0	0

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Participants	0	0	2	1

End point values	Part 2: BMS	Part 2: BMS	Part 3: BMS 20	Part 3: BMS 40
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	160 mg + Nivo 240 mg Q2W	320 mg + Nivo 240 mg Q2W	mg + Ipi 1 mg/kg Q3W	mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	9
Units: Participants	1	1	0	0

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	5	18
Units: Participants	0	0	0	1

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/B MS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Participants	0	0	1	0

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Participants	0	2	0	0

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[9]	
Units: Participants	0	0		

Notes:

[9] - BOR was not evaluable for the only patient because of death prior to any tumor assessment.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR) ^[10]
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End point description:

The time between the date of first response and the subsequent date of disease progression or death (death after re-treatment will not be considered), whichever occurs first in participants with a best overall response (BOR) of complete response (CR) or partial response (PR). Baseline is defined as the last non-missing measurement prior to the first dosing date and time.

End point type	Secondary
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End point timeframe:

From baseline up to approximately 2.5 years

Notes:

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

Justification: Endpoint is specific to Parts 1-8 only

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[11]	0 ^[12]	0 ^[13]	0 ^[14]
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[11] - The number of responders within each tumor type was not sufficient for analysis.

[12] - The number of responders within each tumor type was not sufficient for analysis.

[13] - The number of responders within each tumor type was not sufficient for analysis.

[14] - The number of responders within each tumor type was not sufficient for analysis.

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[15]	0 ^[16]	0 ^[17]	0 ^[18]
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[15] - The number of responders within each tumor type was not sufficient for analysis.

[16] - The number of responders within each tumor type was not sufficient for analysis.

[17] - The number of responders within each tumor type was not sufficient for analysis.

[18] - The number of responders within each tumor type was not sufficient for analysis.

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[19]	0 ^[20]	0 ^[21]	0 ^[22]
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

- [19] - The number of responders within each tumor type was not sufficient for analysis.
 [20] - The number of responders within each tumor type was not sufficient for analysis.
 [21] - The number of responders within each tumor type was not sufficient for analysis.
 [22] - The number of responders within each tumor type was not sufficient for analysis.

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[23]	0 ^[24]	0 ^[25]	0 ^[26]
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

- [23] - The number of responders within each tumor type was not sufficient for analysis.
 [24] - The number of responders within each tumor type was not sufficient for analysis.
 [25] - The number of responders within each tumor type was not sufficient for analysis.
 [26] - The number of responders within each tumor type was not sufficient for analysis.

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W	Part 6B: BMS 40 mg + Nivo 240 mg + Ipi 1mg/kg Q3W/BMS 40 mg + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[27]	0 ^[28]	0 ^[29]	0 ^[30]
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

- [27] - The number of responders within each tumor type was not sufficient for analysis.
 [28] - The number of responders within each tumor type was not sufficient for analysis.
 [29] - The number of responders within each tumor type was not sufficient for analysis.
 [30] - The number of responders within each tumor type was not sufficient for analysis.

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[31]	0 ^[32]	0 ^[33]	0 ^[34]
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

- [31] - The number of responders within each tumor type was not sufficient for analysis.
 [32] - The number of responders within each tumor type was not sufficient for analysis.
 [33] - The number of responders within each tumor type was not sufficient for analysis.
 [34] - The number of responders within each tumor type was not sufficient for analysis.

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[35]	0 ^[36]		
Units: Weeks				
median (confidence interval 95%)	(to)	(to)		

Notes:

[35] - The number of responders within each tumor type was not sufficient for analysis.

[36] - The number of responders within each tumor type was not sufficient for analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS) Rate at 24 Weeks

End point title	Progression Free Survival (PFS) Rate at 24 Weeks ^[37]
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End point description:

The number of treated participants remaining progression free and surviving at 24 weeks since the first dosing date.

99999- Data could not be calculated due to number at risk being less than 5

End point type	Secondary
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End point timeframe:

24 weeks after first dose

Notes:

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

Justification: Endpoint is specific to Parts 1-8 only

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Percent of Participants				
number (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Percent of Participants				
number (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10

Units: Percent of Participants				
number (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Percent of Participants				
number (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg	Part 6B: BMS 40 mg + Nivo 240 mg + Ipi 1mg/kg Q3W/BMS 40 mg + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Percent of Participants				
number (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Percent of Participants				
number (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	2		
Units: Percent of Participants				
number (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax: Maximum observed serum concentration

End point title	Cmax: Maximum observed serum concentration
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End point description:

The maximum observed serum concentration was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	4964 (± 99999)	11245 (± 99999)	19254 (± 99999)	36143 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	23200 (± 99999)	61500 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	68774 (± 99999)	9424 (± 99999)	11699 (± 99999)	19547 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	17392 (± 99999)	23097 (± 99999)
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End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	39182 (± 99999)	76445 (± 99999)	7860 (± 99999)	9345 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	8960 (± 99999)	10273 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	72991 (± 99999)	207853 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	17979 (± 99999)	55790 (± 99999)	65472 (± 99999)	17586 (± 99999)
CYCLE 4 DAY 1	20900 (± 99999)	69922 (± 99999)	117839 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	30922 (± 99999)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W	Part 6B: BMS 40 mg + Nivo 240 mg + Ipi 1mg/kg Q3W/BMS 40 mg + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: NG/ML				
geometric mean (geometric coefficient of variation)				

CYCLE 1 DAY 1	19012 (± 99999)	21399 (± 99999)	11139 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	31800 (± 99999)	11261 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	16912 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	14267 (± 99999)	15424 (± 99999)	3270 (± 99999)	11300 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	14143 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[38]	
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[38] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax: Time of maximum observed serum concentration

End point title	Tmax: Time of maximum observed serum concentration
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End point description:

The time of maximum observed serum concentration was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Hours				
median (full range (min-max))				
CYCLE 1 DAY 1	0.675 (0.467 to 4.52)	0.575 (0.467 to 0.933)	4.58 (0.500 to 24.0)	2.30 (0.567 to 4.02)
CYCLE 4 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CYCLE 5 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CYCLE 9 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	0.467 (0.467 to 0.467)	22.7 (22.7 to 22.7)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Hours				
median (full range (min-max))				
CYCLE 1 DAY 1	0.558 (0.467 to 4.08)	0.467 (0.467 to 4.00)	2.34 (0.467 to 4.08)	0.517 (0.467 to 4.50)
CYCLE 4 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CYCLE 5 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CYCLE 9 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	0.567 (0.467 to 4.00)	4.47 (4.02 to 4.50)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Hours				
median (full range (min-max))				

CYCLE 1 DAY 1	0.650 (0.517 to 4.10)	0.792 (0.450 to 4.50)	0.667 (0.633 to 4.08)	4.00 (0.467 to 4.13)
CYCLE 4 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	0.583 (0.583 to 0.583)	4.00 (0.617 to 24.0)
CYCLE 5 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CYCLE 9 DAY 1	2.38 (0.633 to 4.12)	4.05 (3.98 to 23.9)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Hours				
median (full range (min-max))				
CYCLE 1 DAY 1	4.00 (0.467 to 4.43)	2.55 (0.467 to 24.1)	4.13 (0.467 to 4.62)	4.09 (0.467 to 4.82)
CYCLE 4 DAY 1	0.583 (0.583 to 0.583)	4.00 (0.467 to 24.9)	2.58 (0.467 to 4.68)	99999 (99999 to 99999)
CYCLE 5 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CYCLE 9 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	3.94 (0.500 to 4.03)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Hours				
median (full range (min-max))				
CYCLE 1 DAY 1	0.550 (0.500 to 24.0)	2.30 (0.467 to 4.55)	0.583 (0.467 to 4.08)	99999 (99999 to 99999)
CYCLE 4 DAY 1	99999 (99999 to 99999)	4.03 (4.03 to 4.03)	0.517 (0.500 to 0.583)	99999 (99999 to 99999)
CYCLE 5 DAY 1	0.550 (0.517 to 0.583)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CYCLE 9 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Hours				
median (full range (min-max))				
CYCLE 1 DAY 1	4.00 (0.517 to 23.0)	0.475 (0.467 to 4.75)	0.533 (0.533 to 0.533)	4.83 (4.83 to 4.83)
CYCLE 4 DAY 1	99999 (99999 to 99999)	0.467 (0.000 to 4.00)	99999 (99999 to 99999)	99999 (99999 to 99999)
CYCLE 5 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CYCLE 9 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[39]	
Units: Hours				
median (full range (min-max))				
CYCLE 1 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
CYCLE 4 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
CYCLE 5 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	
CYCLE 9 DAY 1	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)	

Notes:

[39] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-t): Area under the serum concentration-time curve from time 0 to time t

End point title	AUC(0-t): Area under the serum concentration-time curve from time 0 to time t
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End point description:

The area under the serum concentration-time curve from time 0 to time t was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	577541 (± 99999)	1678196 (± 99999)	1825502 (± 99999)	5024906 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	3952990 (± 99999)	13024914 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	9981469 (± 99999)	609426 (± 99999)	1495494 (± 99999)	2324225 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	2971409 (± 99999)	1247687 (± 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	5458640 (± 99999)	8694104 (± 99999)	1047354 (± 99999)	1197507 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	773957 (± 99999)	2210404 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	16483279 (± 99999)	28499982 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	2774058 (± 99999)	7257441 (± 99999)	10580541 (± 99999)	2351794 (± 99999)
CYCLE 4 DAY 1	2400433 (± 99999)	10729551 (± 99999)	23851864 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	4537054 (± 99999)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	2000522 (± 99999)	3216650 (± 99999)	1251698 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	2699238 (± 99999)	1837861 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	2520673 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	1653102 (± 99999)	864500 (± 99999)	390424 (± 99999)	2399055 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	504998 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
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End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[40]	
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[40] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(TAU): Area under the serum concentration-time curve in 1 dosing interval

End point title	AUC(TAU): Area under the serum concentration-time curve in 1 dosing interval
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End point description:

The area under the serum concentration-time curve in 1 dosing interval was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	577541 (± 99999)	1599886 (± 99999)	3142196 (± 99999)	5854143 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	3952990 (± 99999)	13024914 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	9981469 (± 99999)	663257 (± 99999)	1515139 (± 99999)	2551115 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	3345948 (± 99999)	3307867 (± 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	5458640 (± 99999)	11483961 (± 99999)	1383126 (± 99999)	1521223 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	2210404 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	16483279 (± 99999)	50254284 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	3133192 (± 99999)	7464248 (± 99999)	11966698 (± 99999)	2602049 (± 99999)

CYCLE 4 DAY 1	99999 (± 99999)	12666237 (± 99999)	27936423 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	6176469 (± 99999)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	2734577 (± 99999)	3500606 (± 99999)	1568004 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	1837861 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	3335668 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	1705864 (± 99999)	1410042 (± 99999)	447709 (± 99999)	2812249 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	3590883 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
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Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[41]	
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[41] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: Ctau: Observed serum concentration at the end of a dosing interval when intensive samples are collected

End point title	Ctau: Observed serum concentration at the end of a dosing interval when intensive samples are collected
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End point description:

The observed serum concentration at the end of a dosing interval when intensive samples are collected was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	657 (± 99999)	2577 (± 99999)	5354 (± 99999)	10852 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	6470 (± 99999)	33600 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	16514 (\pm 99999)	756 (\pm 99999)	1904 (\pm 99999)	3598 (\pm 99999)
CYCLE 4 DAY 1	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)
CYCLE 5 DAY 1	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)
CYCLE 9 DAY 1	99999 (\pm 99999)	99999 (\pm 99999)	5510 (\pm 99999)	5686 (\pm 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	10413 (\pm 99999)	18596 (\pm 99999)	885 (\pm 99999)	604 (\pm 99999)
CYCLE 4 DAY 1	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)	2527 (\pm 99999)
CYCLE 5 DAY 1	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)
CYCLE 9 DAY 1	34303 (\pm 99999)	131520 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	2335 (\pm 99999)	3059 (\pm 99999)	7739 (\pm 99999)	3928 (\pm 99999)
CYCLE 4 DAY 1	99999 (\pm 99999)	7729 (\pm 99999)	32982 (\pm 99999)	99999 (\pm 99999)
CYCLE 5 DAY 1	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)
CYCLE 9 DAY 1	99999 (\pm 99999)	99999 (\pm 99999)	99999 (\pm 99999)	13400 (\pm 99999)

End point values	Part 4: BMS 80 mg + Nivo	Part 5: BMS 80 mg + Ipi 3	Part 6A: BMS40mg+	Part6B: BMS40 mg+Niv
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	480mg Q4W	mg/kg Q3W	o 240mg+Ipi 1mg/kgQ3W/B MS 40mg+Nivo480 mgQ4W	o240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	544 (± 99999)	1725 (± 99999)	790 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	1262 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	1412 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	1535 (± 99999)	1533 (± 99999)	0.004 (± 99999)	42.9 (± 99999)
CYCLE 4 DAY 1	99999 (± 99999)	6906 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[42]	
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
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Notes:

[42] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: CLT: Total body clearance

End point title	CLT: Total body clearance
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End point description:

The total body clearance was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: L/H				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	0.020 (± 99999)	0.012 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: L/H				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	0.012 (± 99999)	0.024 (± 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: L/H				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.018 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	0.010 (± 99999)	0.006 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: L/H				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	0.013 (± 99999)	0.011 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.013 (± 99999)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W	Part 6B: BMS 40 mg + Nivo 240 mg + Ipi 1mg/kg Q3W/BMS 40 mg + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: L/H				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	0.022 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	0.024 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: L/H				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	0.011 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[43]	
Units: L/H				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[43] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: Css-avg: Average concentration over a dosing interval (AUC(TAU)/tau)

End point title	Css-avg: Average concentration over a dosing interval (AUC(TAU)/tau)
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End point description:

The average concentration over a dosing interval (AUC(TAU)/tau) was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	11826 (± 99999)	45155 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	9746 (± 99999)	9903 (± 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	4379 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	45878 (± 99999)	148579 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1	Part 3: BMS 160 mg + Ipi 1	Part 3: BMS 320 mg + Ipi 1	Part 2C: BMS 80 mg + Nivo
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	mg/kg Q3W	mg/kg Q3W	mg/kg Q3W	240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	25131 (± 99999)	55386 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	19538 (± 99999)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	3715 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	4964 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	10739 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 8: Cohort	Part 8: Cohort	Part 9: BMS 40	
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	3- BMS 80 mg Q12W + Nivo 480 mg Q4W	4- Nivo 480 mg Q4W	mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[44]	
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[44] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: AI: Accumulation Index. Ratio of an exposure measure at steady state (C_{max})

End point title	AI: Accumulation Index. Ratio of an exposure measure at steady state (C _{max})
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End point description:

The ratio of an exposure measure at steady state to that after the first dose was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	1.45 (± 99999)	1.89 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	1.40 (± 99999)	1.29 (± 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	0.793 (± 99999)	1.05 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	1.83 (± 99999)	2.56 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	1.67 (± 99999)	1.40 (± 99999)	1.52 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1.66 (± 99999)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W / BMS 40mg + Nivo 480mg Q4W	Part 6B: BMS 40 mg + Nivo 240 mg + Ipi 1mg/kg Q3W / BMS 40 mg + Nivo 480 mg Q4W
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	1.32 (± 99999)	1.03 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	1.02 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	1.21 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[45]	
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[45] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: AI: Accumulation Index. Ratio of an exposure measure at steady state (AUC)

End point title	AI: Accumulation Index. Ratio of an exposure measure at steady state (AUC)
End point description: The ratio of an exposure measure at steady state to that after the first dose was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A	
End point type	Secondary
End point timeframe: Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)	

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	2.21 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	1.85 (± 99999)	0.748 (± 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				

CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1.28 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	2.78 (± 99999)	4.40 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	1.56 (± 99999)	1.77 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	2.32 (± 99999)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	0.000 (± 99999)	1.37 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	1.21 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: H*NG/ML				
geometric mean (geometric coefficient				

of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	2.13 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[46]	
Units: H*NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[46] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: AI: Accumulation Index. Ratio of an exposure measure at steady state (Ctau)

End point title	AI: Accumulation Index. Ratio of an exposure measure at steady state (Ctau)
End point description:	
The ratio of an exposure measure at steady state to that after the first dose was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A	
End point type	Secondary
End point timeframe:	
Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)	

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: NG/ML				
geometric mean (geometric coefficient of variation)				

CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	2.33 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	2.40 (± 99999)	1.22 (± 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1.90 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	2.61 (± 99999)	7.55 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	1.22 (± 99999)	1.89 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	3.49 (± 99999)
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End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	0.000 (± 99999)	2.47 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	1.05 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	2.72 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[47]	
Units: NG/ML				
geometric mean (geometric coefficient of variation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[47] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: T-HALFeff: Effective elimination half-life that explains the degree of accumulation observed for a specific exposure measure (exposure measure includes AUC(TAU), Cmax)

End point title	T-HALFeff: Effective elimination half-life that explains the degree of accumulation observed for a specific exposure measure (exposure measure includes AUC(TAU), Cmax)
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End point description:

The effective elimination half-life that explains the degree of accumulation observed for a specific exposure measure was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-9 timepoints can include (Pre-dose, 0.30, 4, 24, 72, 168, 336, 696 hours post dose)

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: Hr				
arithmetic mean (standard deviation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	0.000 (± 99999)	331 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: Hr				
arithmetic mean (standard deviation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	315 (± 119)	0.000 (± 0.000)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: Hr				
arithmetic mean (standard deviation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	229 (± 40)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	593 (± 308)	607 (± 527)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: Hr				
arithmetic mean (standard deviation)				
CYCLE 4 DAY 1	99999 (± 99999)	345 (± 111)	429 (± 182)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	312 (± 180)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg	Part 6B: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/BMS 40mg + Nivo 480mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: Hr				
arithmetic mean (standard deviation)				
CYCLE 4 DAY 1	99999 (± 99999)	0.000 (± 99999)	261 (± 58)	99999 (± 99999)
CYCLE 5 DAY 1	447 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: Hr				
arithmetic mean (standard deviation)				
CYCLE 4 DAY 1	99999 (± 99999)	146 (± 200)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[48]	
Units: Hr				
arithmetic mean (standard deviation)				
CYCLE 4 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[48] - Only participants with available serum time-concentration data evaluated

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough: Trough observed plasma concentration

End point title	Ctrough: Trough observed plasma concentration
End point description:	
Trough observed plasma concentration (this includes predose concentrations and Ctau concentrations) was measured after dosing to assess the pharmacokinetics of BMS-986178 administered alone or in combination with Nivolumab and/or Ipilimumab Note: 99999 = N/A	
End point type	Secondary
End point timeframe:	
Cycle 1-17 timepoints can include (Pre-dose, 336, 504, 672 hours post dose)	

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	4
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 29 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 1 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 336 h	657 (± 99999)	2372 (± 99999)	5354 (± 99999)	10852 (± 99999)
CYCLE 2 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 3 DAY 1 0 h	1290 (± 99999)	4244 (± 99999)	5903 (± 99999)	16974 (± 99999)
CYCLE 4 DAY 1 0 h	3420 (± 99999)	4593 (± 99999)	7169 (± 99999)	20703 (± 99999)
CYCLE 4 DAY 29 0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1 0 h	99999 (± 99999)	6600 (± 99999)	13491 (± 99999)	13300 (± 99999)
CYCLE 5 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 7 DAY 1 0 h	99999 (± 99999)	5390 (± 99999)	10217 (± 99999)	22073 (± 99999)
CYCLE 9 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	6300 (± 99999)	31300 (± 99999)
CYCLE 10 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 10 DAY 1 336 h	99999 (± 99999)	99999 (± 99999)	6470 (± 99999)	33600 (± 99999)
CYCLE 17 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	8	12
Units: ng/mL				
geometric mean (geometric coefficient				

of variation)				
CYCLE 1 DAY 29 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 1 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 336 h	16514 (± 99999)	561 (± 99999)	1995 (± 99999)	4006 (± 99999)
CYCLE 2 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 3 DAY 1 0 h	21571 (± 99999)	614 (± 99999)	1825 (± 99999)	4498 (± 99999)
CYCLE 4 DAY 1 0 h	26090 (± 99999)	358 (± 99999)	2095 (± 99999)	5108 (± 99999)
CYCLE 4 DAY 29 0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1 0 h	35200 (± 99999)	386 (± 99999)	1301 (± 99999)	7468 (± 99999)
CYCLE 5 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 7 DAY 1 0 h	99999 (± 99999)	946 (± 99999)	4777 (± 99999)	12527 (± 99999)
CYCLE 9 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	6397 (± 99999)	13536 (± 99999)
CYCLE 10 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 10 DAY 1 336 h	99999 (± 99999)	1190 (± 99999)	8264 (± 99999)	5686 (± 99999)
CYCLE 17 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	8	4	10
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 29 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 1 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 336 h	10413 (± 99999)	18596 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	456 (± 99999)	591 (± 99999)

CYCLE 2 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 3 DAY 1 0 h	16379 (± 99999)	28282 (± 99999)	323 (± 99999)	2049 (± 99999)
CYCLE 4 DAY 1 0 h	20800 (± 99999)	47108 (± 99999)	1080 (± 99999)	1971 (± 99999)
CYCLE 4 DAY 29 0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1 0 h	26813 (± 99999)	90700 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	2527 (± 99999)
CYCLE 6 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 7 DAY 1 0 h	32753 (± 99999)	76970 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1 0 h	29902 (± 99999)	106710 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 10 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 10 DAY 1 336 h	28988 (± 99999)	131520 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 17 DAY 1 0 h	48500 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	18
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 29 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 1 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	4070 (± 99999)
CYCLE 2 DAY 1 504 h	2401 (± 99999)	1921 (± 99999)	7739 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 3 DAY 1 0 h	4894 (± 99999)	2766 (± 99999)	20410 (± 99999)	5055 (± 99999)
CYCLE 4 DAY 1 0 h	5140 (± 99999)	12649 (± 99999)	32150 (± 99999)	7252 (± 99999)
CYCLE 4 DAY 29 0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

CYCLE 5 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	9811 (± 99999)
CYCLE 5 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	18771 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 7 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	11471 (± 99999)
CYCLE 9 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	12905 (± 99999)
CYCLE 10 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	29100 (± 99999)	99999 (± 99999)
CYCLE 10 DAY 1 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	13400 (± 99999)
CYCLE 17 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	16600 (± 99999)

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	6	7	1
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 29 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 1 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 504 h	99999 (± 99999)	2166 (± 99999)	745 (± 99999)	1030 (± 99999)
CYCLE 2 DAY 1 672 h	676 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 3 DAY 1 0 h	1480 (± 99999)	62.5 (± 99999)	689 (± 2006)	99999 (± 99999)
CYCLE 4 DAY 1 0 h	1466 (± 99999)	99999 (± 99999)	754 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 29 0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1 0 h	1671 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	1262 (± 129)	99999 (± 99999)
CYCLE 6 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 672 h	62.5 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

CYCLE 7 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	579 (± 99999)	99999 (± 99999)
CYCLE 10 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 10 DAY 1 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 17 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	2	2
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 29 0 h	1354 (± 99999)	1108 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 1 DAY 15 336 h	1535 (± 99999)	1912 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 0 h	1391 (± 99999)	1107 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 2 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 3 DAY 1 0 h	99999 (± 99999)	2469 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 1 0 h	99999 (± 99999)	5461 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 29 0	99999 (± 99999)	1856 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 4 DAY 15 336 h	99999 (± 99999)	2130 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 5 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 0 h	99999 (± 99999)	604 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 6 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 7 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 9 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 10 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CYCLE 10 DAY 1 336 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

CYCLE 17 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
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End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	2	0 ^[49]	
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 29 0 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 1 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 2 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 2 DAY 1 336 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 2 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 2 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 3 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 4 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 4 DAY 29 0	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 4 DAY 15 336 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 5 DAY 1 504 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 6 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 6 DAY 1 672 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 7 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 9 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 10 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 10 DAY 1 336 h	99999 (± 99999)	99999 (± 99999)	()	
CYCLE 17 DAY 1 0 h	99999 (± 99999)	99999 (± 99999)	()	

Notes:

[49] - Only participants with available serum time-concentration data evaluated

Statistical analyses

Secondary: Frequency of Positive Anti-Drug Antibodies (ADA) to BMS-986178

End point title	Frequency of Positive Anti-Drug Antibodies (ADA) to BMS-986178 ^[50]
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End point description:

The number of participants with positive anti-drug antibodies (ADA) is assessed to characterize the immunogenicity of BMS-986178 administered alone or in combination with nivolumab and/or ipilimumab. ADA Positive: A participant with at least one ADA-positive sample relative to baseline (ADA negative at baseline or ADA titer to be at least 4-fold or greater (\geq) than baseline positive titer) at any time after initiation of treatment.

End point type	Secondary
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End point timeframe:

Cycle 1-6 timepoints can include (Pre-dose, 696 hours post dose)

Notes:

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

Justification: Endpoint is specific to Participants treated with BMS-986178

End point values	Part 1: BMS 20 mg Q2W	Part 1: BMS 40 mg Q2W	Part 1: BMS 80 mg Q2W	Part 1: BMS 160 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	3	3
Units: Positive anti-drug antibodies (ADA)	0	0	1	0

End point values	Part 1: BMS 320 mg Q2W	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	6
Units: Positive anti-drug antibodies (ADA)	0	3	1	3

End point values	Part 2: BMS 160 mg + Nivo 240 mg Q2W	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	2	5
Units: Positive anti-drug antibodies (ADA)	1	0	1	3

End point values	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	6	0 ^[51]

Units: Positive anti-drug antibodies (ADA)	1	4	2	
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Notes:

[51] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

End point values	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	0 ^[52]	0 ^[53]	0 ^[54]
Units: Positive anti-drug antibodies (ADA)	1			

Notes:

[52] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

[53] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

[54] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[55]	3	1	1
Units: Positive anti-drug antibodies (ADA)		0	0	0

Notes:

[55] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

End point values	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[56]	0 ^[57]		
Units: Positive anti-drug antibodies (ADA)				

Notes:

[56] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

[57] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of Positive Anti-Drug Antibodies (ADA) to Nivolumab

End point title	Frequency of Positive Anti-Drug Antibodies (ADA) to
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End point description:

The number of participants with positive anti-drug antibodies (ADA) is assessed to characterize the immunogenicity of Nivolumab administered with BMS-986178 ADA Positive: A participant with at least one ADA-positive sample relative to baseline (ADA negative at baseline or ADA titer to be at least 4-fold

or greater (\geq) than baseline positive titer) at any time after initiation of treatment.

End point type	Secondary
End point timeframe:	
Cycle 1-6 timepoints can include (Pre-dose, 696 hours post dose)	

Notes:

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

Justification: Endpoint is specific to Participants treated with Nivolumab

End point values	Part 2 BMS 20 mg + Nivo 240 mg Q2W	Part 2: BMS 40 mg + Nivo 240 mg Q2W	Part 2: BMS 80 mg + Nivo 240 mg Q2W	Part 2: BMS 160 mg + Nivo 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	7	8	8
Units: Positive anti-drug antibodies (ADA)	0	1	1	0

End point values	Part 2: BMS 320 mg + Nivo 240 mg Q2W	Part 2C: BMS 80 mg + Nivo 240 mg Q2W (BDC)	Part 4: BMS 80 mg + Nivo 480mg Q4W	Part 6A: BMS 40mg + Nivo 240mg + Ipi 1mg/kg Q3W/ BMS 40mg + Nivo 480
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	17	9	5
Units: Positive anti-drug antibodies (ADA)	0	3	0	0

End point values	Part 6B: BMS 40 mg + Nivo 240 mg + Ipi 1mg/kg Q3W/ BMS 40 mg + Nivo 480 mg Q4W	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	5	9	0 ^[59]
Units: Positive anti-drug antibodies (ADA)	0	1	1	

Notes:

[59] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

End point values	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0 ^[60]	1	0 ^[61]
Units: Positive anti-drug antibodies (ADA)	1		0	

Notes:

[60] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

[61] - Participants with Baseline and at Least One Post-baseline ADA Assessment analyzed only

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of Positive Anti-Drug Antibodies (ADA) to Ipilimumab.

End point title	Frequency of Positive Anti-Drug Antibodies (ADA) to Ipilimumab. ^[62]
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End point description:

The number of participants with anti-drug antibodies (ADA) is assessed to characterize the immunogenicity of Ipilimumab administered with BMS-986178 ADA Positive: A participant with at least one ADA-positive sample relative to baseline (ADA negative at baseline or ADA titer to be at least 4-fold or greater (\geq) than baseline positive titer) at any time after initiation of treatment.

End point type	Secondary
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End point timeframe:

Cycle 1-6 timepoints can include (Pre-dose, 696 hours post dose)

Notes:

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

Justification: Endpoint is specific to Participants treated with Ipilimumab

End point values	Part 3: BMS 20 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 40 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 80 mg + Ipi 1 mg/kg Q3W	Part 3: BMS 160 mg + Ipi 1 mg/kg Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	7	7
Units: Positive anti-drug antibodies (ADA)	0	0	1	0

End point values	Part 3: BMS 320 mg + Ipi 1 mg/kg Q3W	Part 5: BMS 80 mg + Ipi 3 mg/kg Q3W	Part 6A: BMS40mg+ Nivo 240mg+Ipi 1mg/kgQ3W/BMS 40mg+Nivo480	Part6B: BMS40 mg+Nivo240 mg+Ipi1mg/kg Q3W/BMS 40 mg+Nivo480 mgQ4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	1
Units: Positive anti-drug antibodies (ADA)	1	0	0	0

End point values	Part 7A: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W	Part 7B: BMS 40mg Q2W + Nivo 240 mg Q2W + Ipi 1 mg/kg Q6W		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	9		
Units: Positive anti-drug antibodies (ADA)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Showing a Change in Soluble OX40 and Peripheral OX40 Receptor Occupancy Pharmacodynamic Biomarkers in Part 8

End point title	The Number of Participants Showing a Change in Soluble OX40 and Peripheral OX40 Receptor Occupancy Pharmacodynamic Biomarkers in Part 8 ^[63]
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End point description:

The Number of Participants Showing a Change in Soluble OX40 and Peripheral OX40 Receptor Occupancy Pharmacodynamic Biomarkers in Part 8. A threshold of 80% receptor occupancy following treatment was applied. Note: 99999 = N/A

End point type	Secondary
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End point timeframe:

Cycle 1-6 timepoints can include (Pre-dose, 24, 168, 336, 672, 1848 hours post dose)

Notes:

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

Justification: Endpoint is specific to Part 8 only

End point values	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	1	1
Units: Participants				
Soluble OX40	99999	99999	99999	99999
Peripheral OX40 receptor occupancy (CD4+ T cells)	1	2	1	0
Peripheral OX40 receptor occupancy (Tregs)	1	1	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Tumor Pharmacodynamics of BMS-986178 in Combination with Nivolumab or Nivolumab Monotherapy in Part 8

End point title	Tumor Pharmacodynamics of BMS-986178 in Combination with Nivolumab or Nivolumab Monotherapy in Part 8 ^[64]
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End point description:

Tumor pharmacodynamics of BMS-986178 in combination with nivolumab or nivolumab monotherapy

End point type	Secondary
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End point timeframe:

Screening, cycle 1-2 timepoints can include (Pre-dose, 336, 1848 hours post dose)

Notes:

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

Justification: Endpoint is specific to Part 8 only

End point values	Part 8: Cohort 1- BMS 20 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 2- BMS 40 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 3- BMS 80 mg Q12W + Nivo 480 mg Q4W	Part 8: Cohort 4- Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[65]	0 ^[66]	0 ^[67]	0 ^[68]
Units: N/A				
number (not applicable)				

Notes:

[65] - Tumor pharmacodynamic readouts not possible due to only 1 matched pair

[66] - Tumor pharmacodynamic readouts not possible due to only 1 matched pair

[67] - Tumor pharmacodynamic readouts not possible due to only 1 matched pair

[68] - Tumor pharmacodynamic readouts not possible due to only 1 matched pair

Statistical analyses

No statistical analyses for this end point

Secondary: The number of Participants with Sustained T Cell Expansion with DPV-001 in Combination with Nivolumab or Nivolumab Monotherapy in Part 9

End point title	The number of Participants with Sustained T Cell Expansion with DPV-001 in Combination with Nivolumab or Nivolumab Monotherapy in Part 9 ^[69]
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End point description:

The number of participants with Sustained T Cell Expansion with DPV-001 in Combination with Nivolumab or Nivolumab Monotherapy was assessed to show a change in pharmacodynamics biomarkers

End point type	Secondary
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End point timeframe:

Cycle 1-6 timepoints can include (Pre-dose, 24, 168, 336, 672, 1848 hours post dose)

Notes:

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

Justification: Endpoint is specific to Part 9 only

End point values	Part 9: BMS 40 mg Q4W + Nivo 480 mg Q4W + DRibble Vaccine			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[70]			
Units: Participants				
number (not applicable)				

Notes:

[70] - Only participants with available pharmacodynamic data evaluated

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs collected were reported between the first dose and 100 days after the last dose of study medication and on or prior to the first dose of re-treatment.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.1
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Reporting groups

Reporting group title	BMS-986178 ESC 20 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 20 mg BMS-986178 intravenously (IV) over 30 minutes Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 40 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 40 mg BMS-986178 IV over 30 minutes Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 80 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 80 mg BMS-986178 IV over 30 minutes Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 160 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 160 mg BMS-986178 IV over 30 minutes Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 320 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 320 mg BMS-986178 IV over 30 minutes Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 20 MG+NIVO 240 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 20 mg BMS-986178 and 240 mg Nivolumab IV over 30 minutes each separately Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 80 MG+NIVO 240 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 80 mg BMS-986178 and 240 mg Nivolumab IV over 30 minutes each separately Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 40 MG+NIVO 240 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 40 mg BMS-986178 and 240 mg Nivolumab IV over 30 minutes each separately Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 160 MG+NIVO 240 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 160 mg BMS-986178 and 240 mg Nivolumab IV over 30 minutes each separately Q2W upto 24 weeks.

Reporting group title	BMS-986178 EXP 80 MG+NIVO 240 MG (BLADDER CANCER)
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Reporting group description:

Subjects with Bladder cancer were administered 80 mg BMS-986178 and 240 mg Nivolumab IV over 30 minutes each separately Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 320 MG+NIVO 240 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 320 mg BMS-986178 and 240 mg Nivolumab IV

over 30 minutes each separately Q2W upto 24 weeks.

Reporting group title	BMS-986178 ESC 40 MG+IPI 1 MG/KG
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Reporting group description:

Subjects with Advanced solid tumors were administered 40 mg BMS-986178 and 1 mg/kg Ipilimumab IV over 30 minutes each separately Q3W upto 24 weeks.

Reporting group title	BMS-986178 ESC 20 MG+IPI 1 MG/KG
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Reporting group description:

Subjects with Advanced solid tumors were administered 20 mg BMS-986178 and 1 mg/kg Ipilimumab IV over 30 minutes each separately Q3W upto 24 weeks.

Reporting group title	BMS-986178 ESC 80 MG+IPI 1 MG/KG
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Reporting group description:

Subjects with Advanced solid tumors were administered 80 mg BMS-986178 and 1 mg/kg Ipilimumab IV over 30 minutes each separately Q3W upto 24 weeks.

Reporting group title	BMS-986178 ESC 160 MG+IPI 1 MG/KG
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Reporting group description:

Subjects with Advanced solid tumors were administered 160 mg BMS-986178 and 1 mg/kg Ipilimumab IV over 30 minutes each separately Q3W upto 24 weeks.

Reporting group title	BMS-986178 EPL 80 MG+NIVO 480 MG
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Reporting group description:

Subjects with Advanced solid tumors were administered 80 mg BMS-986178 and 480 mg Nivolumab IV over 30 minutes each separately Q4W upto 24 weeks.

Reporting group title	BMS-986178 ESC 320 MG+IPI 1 MG/KG
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Reporting group description:

Subjects with Advanced solid tumors were administered 320 mg BMS-986178 and 1 mg/kg Ipilimumab IV over 30 minutes each separately Q3W upto 24 weeks.

Reporting group title	BMS-986178 EPL 80 MG+IPI 3 MG/KG
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Reporting group description:

Subjects with Advanced solid tumors 80 mg BMS-986178 and 3 mg/kg Ipilimumab IV over 30 minutes each separately Q3W upto 24 weeks.

Reporting group title	BMS-986178 EXP 40 MG+NIVO 240/480 MG+IPI 1 MG/KG (RCC)
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Reporting group description:

Subjects with RCC were administered 40 mg BMS-986178 and 240 mg Nivolumab and 1 mg/kg Ipilimumab Q3W IV over 30 minutes each separately followed by 40 mg BMS-986178 and 480 mg Nivolumab IV over 30 minutes each separately Q4W upto 24 weeks.

Reporting group title	BMS-986178 SAF 40 MG+NIVO 240/480 MG+IPI 1 MG/KG (RCC)
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Reporting group description:

Subjects with Renal cell carcinoma (RCC) were administered 40 mg BMS-986178 and 240 mg Nivolumab and 1 mg/kg Ipilimumab Q3W IV over 30 minutes each separately followed by 40 mg BMS-986178 and 480 mg Nivolumab IV over 30 minutes each separately Q4W upto 24 weeks.

Reporting group title	BMS-986178 SAF 40 MG+NIVO 240 MG+IPI 1 MG/KG (NSCLC)
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Reporting group description:

Subjects with Non-small cell lung cancer (NSCLC) were administered 40 mg BMS-986178 Q2W and 240 mg Nivolumab each separately Q2W and 1 mg/kg Ipilimumab Q6W upto 24 weeks.

Reporting group title	BMS-986178 EPL 20 MG+NIVO 480 MG (BLADDER CANCER)
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Reporting group description:

Subjects with Bladder cancer were administered 20 mg BMS-986178 Q12W and 480 mg Nivolumab IV over 30 minutes each separately Q4W upto 24 months or until protocol specified discontinuation criteria.

Reporting group title	NIVO 480 MG EPL (BLADDER CANCER)
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Reporting group description:

Subjects with Bladder cancer were administered 480 mg Nivolumab IV and Tetanus vaccine intramuscularly on Cycle 1 Day 1 each separately upto 24 months or until protocol specified discontinuation criteria.

Reporting group title	BMS-986178 EPL 40 MG+NIVO 480 MG (BLADDER CANCER)
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Reporting group description:

Subjects with Bladder cancer were administered 40 mg BMS-986178 Q12W and 480 mg Nivolumab IV

over 30 minutes each separately Q4W upto 24 months or until protocol specified discontinuation criteria.

Reporting group title	BMS-986178 EXP 40 MG+NIVO 240 MG+IPI 1 MG/KG (NSCLC)
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Reporting group description:

Subjects with NSCLC were administered 40 mg BMS-986178 Q2W and 240 mg Nivolumab each separately Q2W and 1 mg/kg Ipilimumab Q6W upto 24 weeks.

Reporting group title	BMS-986178 EPL 80 MG+NIVO 480 MG (BLADDER CANCER)
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Reporting group description:

Subjects with Bladder cancer were administered 80 mg BMS-986178 Q12W and 480 mg Nivolumab IV over 30 minutes each separately Q4W upto 24 months or until protocol specified discontinuation criteria.

Reporting group title	BMS-986178 EXP 40 MG+NIVO 480 MG+DPV 1
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Reporting group description:

Subjects with Triple negative Breast cancer were administered 40 mg BMS-986178 Q4W, 480 mg Nivolumab Q4W IV over 30 minutes each separately and 1 mg DPV-001 until end of the treatment.

Serious adverse events	BMS-986178 ESC 20 MG	BMS-986178 ESC 40 MG	BMS-986178 ESC 80 MG
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	4 / 4 (100.00%)	2 / 4 (50.00%)
number of deaths (all causes)	3	2	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant ascites			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Malignant neoplasm progression			
subjects affected / exposed	3 / 4 (75.00%)	2 / 4 (50.00%)	2 / 4 (50.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 1
Metastases to spine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis malignant			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastroenteritis radiation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Cardiac disorders			
Cardiac arrest			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Bell's palsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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	1 / 4 (25.00%)	0 / 4 (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
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psoriatic arthropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Encephalitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Infected fistula			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Cachexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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	BMS-986178 ESC 160 MG	BMS-986178 ESC 320 MG	BMS-986178 ESC 20 MG+NIVO 240 MG
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	3 / 4 (75.00%)	3 / 7 (42.86%)
number of deaths (all causes)	3	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Malignant neoplasm progression			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pericarditis malignant			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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

Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Injury, poisoning and procedural complications			
Gastroenteritis radiation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 arrest			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 tamponade			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Bell's palsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Brain oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hemiparesis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 7 (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
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Duodenitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Large intestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Melaena			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pancreatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 gastrointestinal haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hepatic failure			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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

Psoriatic arthropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Encephalitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Infected fistula			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 7 (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
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Septic shock			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Cachexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hypoglycaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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	BMS-986178 ESC 80 MG+NIVO 240 MG	BMS-986178 ESC 40 MG+NIVO 240 MG	BMS-986178 ESC 160 MG+NIVO 240 MG
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 12 (58.33%)	6 / 8 (75.00%)	4 / 8 (50.00%)
number of deaths (all causes)	5	3	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant ascites			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	5 / 12 (41.67%)	3 / 8 (37.50%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 5	0 / 4	0 / 1
Metastases to spine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis malignant			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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			
Haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (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
Delirium			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (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
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastroenteritis radiation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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 arrest			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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			
Bell's palsy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (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
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haematemesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psoriatic arthropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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			
Encephalitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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 infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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			
Cachexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (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
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (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
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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	BMS-986178 EXP 80 MG+NIVO 240 MG (BLADDER CANCER)	BMS-986178 ESC 320 MG+NIVO 240 MG	BMS-986178 ESC 40 MG+IPI 1 MG/KG
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 18 (61.11%)	5 / 8 (62.50%)	6 / 10 (60.00%)
number of deaths (all causes)	6	4	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant ascites			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	6 / 18 (33.33%)	4 / 8 (50.00%)	5 / 10 (50.00%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 6	0 / 4	0 / 4
Metastases to spine			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (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
Pericarditis malignant			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haemorrhage			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastroenteritis radiation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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 arrest			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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			
Bell's palsy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (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
Hemiparesis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 18 (5.56%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			

subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (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
Melaena			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (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
Hydronephrosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (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

Psoriatic arthropathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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			
Encephalitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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 infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (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
Hypoglycaemia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
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	BMS-986178 ESC 20 MG+IPI 1 MG/KG	BMS-986178 ESC 80 MG+IPI 1 MG/KG	BMS-986178 ESC 160 MG+IPI 1 MG/KG
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	6 / 7 (85.71%)	5 / 8 (62.50%)
number of deaths (all causes)	2	5	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	2 / 4 (50.00%)	5 / 7 (71.43%)	4 / 8 (50.00%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 5	0 / 4
Metastases to spine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis malignant			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (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
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (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

Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastroenteritis radiation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 arrest			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Bell's palsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psoriatic arthropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Encephalitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (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			
Cachexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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	BMS-986178 EPL 80 MG+NIVO 480 MG	BMS-986178 ESC 320 MG+IPI 1 MG/KG	BMS-986178 EPL 80 MG+IPI 3 MG/KG
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 12 (58.33%)	2 / 6 (33.33%)	4 / 6 (66.67%)
number of deaths (all causes)	3	1	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant ascites			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Metastases to spine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis malignant			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 12 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastroenteritis radiation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 arrest			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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			
Bell's palsy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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	2 / 12 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haematemesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psoriatic arthropathy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Encephalitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
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 infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	BMS-986178 EXP 40 MG+NIVO 240/480 MG+IPI 1 MG/KG (RCC)	BMS-986178 SAF 40 MG+NIVO 240/480 MG+IPI 1 MG/KG (RCC)	BMS-986178 SAF 40 MG+NIVO 240 MG+IPI 1 MG/KG (NSCLC)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	4 / 7 (57.14%)	6 / 6 (100.00%)
number of deaths (all causes)	0	2	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 1 (0.00%)	2 / 7 (28.57%)	4 / 6 (66.67%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 4
Metastases to spine			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis malignant			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Haemorrhage			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspartate aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastroenteritis radiation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 arrest			

subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Bell's palsy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Large intestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psoriatic arthropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
Encephalitis			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 7 (28.57%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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	BMS-986178 EPL 20 MG+NIVO 480 MG (BLADDER CANCER)	NIVO 480 MG EPL (BLADDER CANCER)	BMS-986178 EPL 40 MG+NIVO 480 MG (BLADDER CANCER)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 2 (50.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis malignant			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastroenteritis radiation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Bell's palsy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psoriatic arthropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Encephalitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

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

Serious adverse events	BMS-986178 EXP 40 MG+NIVO 240 MG+IPI 1 MG/KG (NSCLC)	BMS-986178 EPL 80 MG+NIVO 480 MG (BLADDER CANCER)	BMS-986178 EXP 40 MG+NIVO 480 MG+DPV 1
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 9 (55.56%)	1 / 2 (50.00%)	1 / 1 (100.00%)
number of deaths (all causes)	1	1	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastases to spine			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis malignant			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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			
Haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (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
Stridor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastroenteritis radiation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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 arrest			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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			
Bell's palsy			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (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
Brain oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (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
Duodenitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psoriatic arthropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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			
Encephalitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Skin infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
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			
Cachexia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (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
Decreased appetite			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	BMS-986178 ESC 20 MG	BMS-986178 ESC 40 MG	BMS-986178 ESC 80 MG
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	4 / 4 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Embolism venous			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Feeling cold			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pleuritic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Affect lability			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradyphrenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ammonia increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	4
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood bilirubin increased			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Blood chloride decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood glucose increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Carbon dioxide decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Lymph node palpable			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Platelet count increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Serum ferritin decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Urine output decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0
Urine protein/creatinine ratio increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	2 / 4 (50.00%) 2	0 / 4 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Injury, poisoning and procedural complications			
Ankle fracture subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Infusion related reaction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular access site occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Nervous system disorders			
Aphasia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1
Balance disorder subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Bell's palsy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Head discomfort subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Lethargy			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 4 (50.00%)
occurrences (all)	0	1	7

Lymph node pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1
Neutropenia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Eye disorders Blepharospasm subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Dry eye subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Eye irritation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	3	0	1
Abdominal pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0

Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	2 / 4 (50.00%)
occurrences (all)	1	1	2
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Diverticulum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 4 (75.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	3	0	1
Odynophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Autoimmune dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Thyroiditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Joint stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight bearing difficulty			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 4 (25.00%) 2
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cryptosporidiosis infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Dehydration			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			

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

Non-serious adverse events	BMS-986178 ESC 160 MG	BMS-986178 ESC 320 MG	BMS-986178 ESC 20 MG+NIVO 240 MG
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	4 / 4 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Embolism venous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Early satiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Feeling cold			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pyrexia			

subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 3	1 / 4 (25.00%) 4	2 / 7 (28.57%) 2
Swelling face subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Temperature regulation disorder subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Immune system disorders Allergy to arthropod sting subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Reproductive system and breast disorders Breast pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Scrotal oedema subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Scrotal pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Bronchospasm subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Cough			

subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Bradyphrenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Depression			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Ammonia increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	3 / 7 (42.86%)
occurrences (all)	1	0	3
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood lactic acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Carbon dioxide decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymph node palpable			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Platelet count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Serum ferritin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Urine output decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urine protein/creatinine ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Weight decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 7 (14.29%) 1
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Injury, poisoning and procedural complications			
Ankle fracture subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Thermal burn			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular access site occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Balance disorder			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bell's palsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	4
Lymph node pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Aphthous ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Diarrhoea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	2
Diverticulum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Large intestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Mouth haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	1 / 4 (25.00%) 2	2 / 7 (28.57%) 2
Odynophagia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Oral pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Retching subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Small intestinal obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Swollen tongue subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0	1 / 7 (14.29%) 1
Hepatobiliary disorders Biliary obstruction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Autoimmune dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperkeratosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2

Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight bearing difficulty			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cryptosporidiosis infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Peritonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 7 (14.29%) 1
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	0 / 7 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Wound infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 2	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Hypernatraemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS-986178 ESC 80 MG+NIVO 240 MG	BMS-986178 ESC 40 MG+NIVO 240 MG	BMS-986178 ESC 160 MG+NIVO 240 MG
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	8 / 8 (100.00%)	6 / 8 (75.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Lymphangiosis carcinomatosa subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Malignant neoplasm progression subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Metastases to central nervous system subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Embolism venous subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 2	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Haemorrhage subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Hypertension subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 3	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 2	0 / 8 (0.00%) 0
Phlebitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	1	3	0
Axillary pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Early satiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 12 (16.67%)	1 / 8 (12.50%)	5 / 8 (62.50%)
occurrences (all)	2	1	6
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Influenza like illness			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Injury associated with device			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Nodule			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 12 (16.67%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	2	1	1
Pyrexia			
subjects affected / exposed	5 / 12 (41.67%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	5	3	0
Swelling face			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Scrotal oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	2 / 12 (16.67%)	0 / 8 (0.00%)	2 / 8 (25.00%)
occurrences (all)	2	0	2
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pulmonary embolism			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Bradyphrenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	2 / 12 (16.67%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Ammonia increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	2 / 8 (25.00%)	1 / 8 (12.50%)
occurrences (all)	2	3	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 12 (8.33%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Blood bilirubin increased			
subjects affected / exposed	1 / 12 (8.33%)	3 / 8 (37.50%)	0 / 8 (0.00%)
occurrences (all)	1	4	0
Blood chloride decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 12 (16.67%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Blood glucose increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Blood urea increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Carbon dioxide decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Lymph node palpable			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	2	2	0
Neutrophil count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Platelet count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine protein/creatinine ratio increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 12 (16.67%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	3	0	2
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Injury, poisoning and procedural complications			
Ankle fracture subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Vascular access complication subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Vascular access site occlusion			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bell's palsy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	3
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Presyncope			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 12 (16.67%)	4 / 8 (50.00%)	1 / 8 (12.50%)
occurrences (all)	8	8	3
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eyelid rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Periorbital oedema subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2	2 / 8 (25.00%) 2	2 / 8 (25.00%) 4
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Anal haemorrhage subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Anorectal discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Aphthous ulcer subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Ascites			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	3
Constipation			
subjects affected / exposed	4 / 12 (33.33%)	2 / 8 (25.00%)	3 / 8 (37.50%)
occurrences (all)	6	2	4
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	5
Diverticulum			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 12 (16.67%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Glossodynia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 12 (25.00%)	1 / 8 (12.50%)	2 / 8 (25.00%)
occurrences (all)	3	1	6
Odynophagia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Vomiting			
subjects affected / exposed	2 / 12 (16.67%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	2	0	4
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cholelithiasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Autoimmune dermatitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Eczema subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Hyperkeratosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Nail disorder subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Psoriasis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 2	0 / 8 (0.00%) 0
Rash			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Rash papular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Skin haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Nephritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Thyroiditis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	2 / 8 (25.00%)
occurrences (all)	1	2	5
Arthritis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	4
Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Joint range of motion decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Musculoskeletal pain			

subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Pain in extremity			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Psoriatic arthropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight bearing difficulty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	3
Candida infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0

Cryptosporidiosis infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Peritonitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	3	0	1
Rash pustular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 8 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1

Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Wound infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	1 / 8 (12.50%) 1	2 / 8 (25.00%) 2
Dehydration subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 2	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 4	2 / 8 (25.00%) 3	0 / 8 (0.00%) 0
Hypernatraemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 2	0 / 8 (0.00%) 0
Hypoalbuminaemia			

subjects affected / exposed	0 / 12 (0.00%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Hyponatraemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 12 (8.33%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	BMS-986178 EXP 80 MG+NIVO 240 MG (BLADDER CANCER)	BMS-986178 ESC 320 MG+NIVO 240 MG	BMS-986178 ESC 40 MG+IPI 1 MG/KG
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 18 (100.00%)	8 / 8 (100.00%)	10 / 10 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Metastases to central nervous system			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	4	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	2 / 18 (11.11%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Hypotension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	1	3	0
Axillary pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Early satiety			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	7 / 18 (38.89%)	4 / 8 (50.00%)	2 / 10 (20.00%)
occurrences (all)	9	5	3
Feeling cold			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Malaise			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	4 / 18 (22.22%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	5	1	0
Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	4 / 18 (22.22%)	2 / 8 (25.00%)	4 / 10 (40.00%)
occurrences (all)	4	2	4
Swelling face			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Temperature regulation disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			

subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Scrotal oedema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Scrotal pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Vaginal discharge			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 18 (11.11%)	2 / 8 (25.00%)	1 / 10 (10.00%)
occurrences (all)	2	3	2
Dysphonia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 18 (5.56%)	1 / 8 (12.50%)	2 / 10 (20.00%)
occurrences (all)	2	1	2
Dyspnoea exertional			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Epistaxis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	3	0
Hiccups			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 18 (5.56%)	1 / 8 (12.50%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Pulmonary embolism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Respiratory tract congestion			

subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Rhinitis allergic subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Sinus congestion subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	1 / 10 (10.00%) 1
Wheezing subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 8 (12.50%) 1	0 / 10 (0.00%) 0
Psychiatric disorders			
Affect lability subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 8 (12.50%) 2	0 / 10 (0.00%) 0
Bradyphrenia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Confusional state subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Depression subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	1 / 10 (10.00%) 1
Insomnia subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	1 / 8 (12.50%) 1	0 / 10 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Ammonia increased			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	3 / 18 (16.67%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	5	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	5 / 18 (27.78%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	6	0	0
Blood glucose increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	5	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Carbon dioxide decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	3 / 18 (16.67%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	7	0	1
Lymph node palpable			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urine protein/creatinine ratio increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	2 / 10 (20.00%)
occurrences (all)	2	0	3
Weight increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

White blood cell count increased subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Injury, poisoning and procedural complications			
Ankle fracture subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	1 / 10 (10.00%) 1
Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Vascular access complication subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Vascular access site occlusion subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Cardiac disorders			

Arrhythmia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bell's palsy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Dysgeusia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	1 / 18 (5.56%)	2 / 8 (25.00%)	1 / 10 (10.00%)
occurrences (all)	1	2	1
Hypoaesthesia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 18 (5.56%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	1	3	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 18 (44.44%)	1 / 8 (12.50%)	3 / 10 (30.00%)
occurrences (all)	16	2	3
Lymph node pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Vertigo			

subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eyelid rash			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Vision blurred subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	1 / 10 (10.00%) 1
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	1 / 10 (10.00%) 1
Abdominal pain subjects affected / exposed occurrences (all)	3 / 18 (16.67%) 3	0 / 8 (0.00%) 0	1 / 10 (10.00%) 1
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	1 / 10 (10.00%) 1
Anal haemorrhage subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Anorectal discomfort subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Aphthous ulcer subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	1 / 10 (10.00%) 1
Constipation			

subjects affected / exposed	3 / 18 (16.67%)	1 / 8 (12.50%)	5 / 10 (50.00%)
occurrences (all)	4	1	5
Diarrhoea			
subjects affected / exposed	4 / 18 (22.22%)	0 / 8 (0.00%)	2 / 10 (20.00%)
occurrences (all)	6	0	2
Diverticulum			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Dyspepsia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Glossodynia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Haemorrhoids			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Nausea			

subjects affected / exposed	0 / 18 (0.00%)	2 / 8 (25.00%)	2 / 10 (20.00%)
occurrences (all)	0	3	2
Odynophagia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Swollen tongue			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 18 (0.00%)	2 / 8 (25.00%)	2 / 10 (20.00%)
occurrences (all)	0	2	4
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Autoimmune dermatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Nail disorder			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	3 / 10 (30.00%)
occurrences (all)	2	0	3
Psoriasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	2 / 10 (20.00%)
occurrences (all)	1	0	2
Rash erythematous			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Skin disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Micturition urgency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Pollakiuria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Renal failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 18 (0.00%)	2 / 8 (25.00%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Thyroiditis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Arthritis			
subjects affected / exposed	1 / 18 (5.56%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Back pain			

subjects affected / exposed	3 / 18 (16.67%)	2 / 8 (25.00%)	1 / 10 (10.00%)
occurrences (all)	7	2	1
Bone pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Bursitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Joint range of motion decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 18 (0.00%)	3 / 8 (37.50%)	0 / 10 (0.00%)
occurrences (all)	0	6	0
Muscle twitching			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	3 / 18 (16.67%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	4	1	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Weight bearing difficulty			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	1 / 18 (5.56%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Cellulitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cryptosporidiosis infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Cystitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Nail infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Oral candidiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 8 (12.50%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Sputum purulent			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	2 / 18 (11.11%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Wound infection subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	3 / 18 (16.67%) 4	7 / 8 (87.50%) 9	2 / 10 (20.00%) 2
Dehydration subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	1 / 8 (12.50%) 9	0 / 10 (0.00%) 0
Hypernatraemia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 3	0 / 8 (0.00%) 0	0 / 10 (0.00%) 0
Hypocalcaemia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 8 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS-986178 ESC 20 MG+IPI 1 MG/KG	BMS-986178 ESC 80 MG+IPI 1 MG/KG	BMS-986178 ESC 160 MG+IPI 1 MG/KG
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	7 / 7 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tumour pain			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Embolism venous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Thrombophlebitis superficial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 8 (25.00%)
occurrences (all)	0	1	5
Axillary pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 8 (25.00%)
occurrences (all)	0	1	5
Feeling cold			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mass			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	2 / 8 (25.00%)
occurrences (all)	1	2	3
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Pleuritic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Bradyphrenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 4 (50.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Ammonia increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Amylase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 4 (50.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	5
Blood glucose increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Carbon dioxide decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymph node palpable			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Neutrophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine protein/creatinine ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Weight increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
White blood cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	5
Muscle strain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vascular access complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular access site occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bell's palsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Head discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Taste disorder subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Tremor subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 7 (28.57%) 4	3 / 8 (37.50%) 8
Lymph node pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Eye disorders			
Blepharospasm subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Cataract			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Eyelid rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Macular degeneration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Anorectal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 8 (25.00%)
occurrences (all)	0	1	5
Diverticulum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	2 / 8 (25.00%)
occurrences (all)	2	2	2
Odynophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Retching subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Small intestinal obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Swollen tongue subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 3	1 / 7 (14.29%) 1	1 / 8 (12.50%) 2
Hepatobiliary disorders Biliary obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Cholelithiasis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Autoimmune dermatitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Dry skin			

subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	4	3
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Renal failure subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Urinary retention subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Thyroiditis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 7 (14.29%) 2	0 / 8 (0.00%) 0
Arthritis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Bone pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Bursitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Flank pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Muscle twitching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Psoriatic arthropathy			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Weight bearing difficulty			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cryptosporidiosis infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Rash pustular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sputum purulent			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	3 / 8 (37.50%)
occurrences (all)	1	0	4
Dehydration			

subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Hypomagnesaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	5
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS-986178 EPL 80 MG+NIVO 480 MG	BMS-986178 ESC 320 MG+IPI 1 MG/KG	BMS-986178 EPL 80 MG+IPI 3 MG/KG
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 12 (91.67%)	6 / 6 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tumour pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Embolism venous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Phlebitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	3 / 6 (50.00%)
occurrences (all)	1	0	3
Early satiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 12 (25.00%)	2 / 6 (33.33%)	4 / 6 (66.67%)
occurrences (all)	3	2	5
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	3 / 12 (25.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Swelling face			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 12 (0.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	3	1
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	4 / 12 (33.33%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	4	1	2
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hiccups			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			

subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Pulmonary haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Respiratory tract congestion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Affect lability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bradyphrenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Ammonia increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Amylase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood chloride increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	2	1	7
Blood glucose increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood phosphorus decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Carbon dioxide decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Lipase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lymph node palpable			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Neutrophil count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Platelet count increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Serum ferritin decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Urine output decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Urine protein/creatinine ratio increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
Weight decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	2 / 6 (33.33%) 2	1 / 6 (16.67%) 1
Weight increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
Injury, poisoning and procedural complications			
Ankle fracture subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Infusion related reaction			

subjects affected / exposed	1 / 12 (8.33%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Muscle strain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular access site occlusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Nervous system disorders			
Aphasia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Balance disorder subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Bell's palsy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Head discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Lethargy			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 12 (41.67%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	13	5	2

Lymph node pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 2	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Eye disorders Blepharospasm subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 6 (16.67%) 1	0 / 6 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Dry eye subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
Eye irritation			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eyelid rash			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 12 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	6	1	0

Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Anal haemorrhage subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Anorectal discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 6 (16.67%) 1	0 / 6 (0.00%) 0
Aphthous ulcer subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
Ascites subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
Constipation subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2	3 / 6 (50.00%) 4	2 / 6 (33.33%) 2
Diarrhoea subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2	2 / 6 (33.33%) 5	1 / 6 (16.67%) 1
Diverticulum subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Dry mouth subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1
Dyspepsia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Dysphagia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0

Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 12 (25.00%)	0 / 6 (0.00%)	4 / 6 (66.67%)
occurrences (all)	3	0	6
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 12 (16.67%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	2	1	2
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Autoimmune dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 12 (25.00%)	2 / 6 (33.33%)	3 / 6 (50.00%)
occurrences (all)	4	2	5
Psoriasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Rash erythematous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Renal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Hypothyroidism			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Thyroiditis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 12 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Joint range of motion decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Spinal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight bearing difficulty			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cryptosporidiosis infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 12 (8.33%)	2 / 6 (33.33%)	3 / 6 (50.00%)
occurrences (all)	1	3	4
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Hypercalcaemia			

subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	6
Hypernatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS-986178 EXP 40 MG+NIVO 240/480 MG+IPI 1 MG/KG (RCC)	BMS-986178 SAF 40 MG+NIVO 240/480 MG+IPI 1 MG/KG (RCC)	BMS-986178 SAF 40 MG+NIVO 240 MG+IPI 1 MG/KG (NSCLC)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	5 / 7 (71.43%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Metastases to central nervous system			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hot flush			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Phlebitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	4
Axillary pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	1	2
Early satiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	1 / 1 (100.00%)	3 / 7 (42.86%)	1 / 6 (16.67%)
occurrences (all)	1	5	2
Feeling cold			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Mass			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0
Swelling face subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Temperature regulation disorder subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0
Immune system disorders Allergy to arthropod sting subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Reproductive system and breast disorders Breast pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Scrotal oedema subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Scrotal pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			

Bronchospasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 1 (100.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	1	1	2
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 1 (100.00%)	2 / 7 (28.57%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pleuritic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Bradyphrenia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ammonia increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood glucose increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Carbon dioxide decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			

subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Lymph node palpable			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Platelet count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Urine output decreased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Urine protein/creatinine ratio increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 1	0 / 7 (0.00%) 0	1 / 6 (16.67%) 2
Weight increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Injury, poisoning and procedural complications			
Ankle fracture subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	2 / 6 (33.33%) 4
Muscle strain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Post procedural haemorrhage			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular access site occlusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Cardiac failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Supraventricular tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bell's palsy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Head discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Migraine			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 7 (28.57%)	1 / 6 (16.67%)
occurrences (all)	0	4	3
Lymph node pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eyelid rash			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vitreous floaters			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Anal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Diarrhoea			
subjects affected / exposed	1 / 1 (100.00%)	3 / 7 (42.86%)	1 / 6 (16.67%)
occurrences (all)	2	3	1
Diverticulum			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1

Glossodynia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 1 (100.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Odynophagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Swollen tongue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Vomiting subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 7 (14.29%) 1	1 / 6 (16.67%) 1
Hepatobiliary disorders			
Biliary obstruction subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Cholelithiasis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Autoimmune dermatitis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Hyperkeratosis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Nail disorder			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	2	2
Psoriasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nephritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Arthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Bone pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Bursitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			

subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Psoriatic arthropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight bearing difficulty			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Abdominal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cryptosporidiosis infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Nail infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Skin infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	3 / 6 (50.00%)
occurrences (all)	1	0	3
Dehydration			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	3
Diabetes mellitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS-986178 EPL 20 MG+NIVO 480 MG (BLADDER CANCER)	NIVO 480 MG EPL (BLADDER CANCER)	BMS-986178 EPL 40 MG+NIVO 480 MG (BLADDER CANCER)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	2 / 2 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Axillary pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Early satiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Feeling cold			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Swelling face			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Temperature regulation disorder subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Immune system disorders Allergy to arthropod sting subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Reproductive system and breast disorders Breast pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Scrotal oedema subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Scrotal pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Bronchospasm subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Dysphonia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bradyphrenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ammonia increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	5	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	6	0
Blood chloride decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Carbon dioxide decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Lymph node palpable			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urine protein/creatinine ratio increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1

Weight increased subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Injury, poisoning and procedural complications			
Ankle fracture subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vascular access complication			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular access site occlusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Bell's palsy			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Head discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Memory impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 2 (100.00%)	1 / 2 (50.00%)
occurrences (all)	0	3	2
Lymph node pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Periorbital oedema subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Anal haemorrhage subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Anorectal discomfort subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Aphthous ulcer			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Diverticulum			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Cholelithiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Autoimmune dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Psoriasis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Micturition urgency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 2 (50.00%)
occurrences (all)	0	2	1
Arthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0

Musculoskeletal discomfort subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Psoriatic arthropathy subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Rotator cuff syndrome subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Spinal pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Weight bearing difficulty subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Infections and infestations			
Abdominal infection subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Candida infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cryptosporidiosis infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	1 / 2 (50.00%)
occurrences (all)	1	1	3
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Hyperuricaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS-986178 EXP 40 MG+NIVO 240 MG+IPI 1 MG/KG (NSCLC)	BMS-986178 EPL 80 MG+NIVO 480 MG (BLADDER CANCER)	BMS-986178 EXP 40 MG+NIVO 480 MG+DPV 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	2 / 2 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Malignant neoplasm progression subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Metastases to central nervous system subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Embolism subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Embolism venous subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Haemorrhage subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Phlebitis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Thrombophlebitis superficial			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 9 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0
Axillary pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Early satiety			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	4 / 9 (44.44%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	7	2	0
Feeling cold			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Nodule			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Swelling face			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Allergy to arthropod sting subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 2 (50.00%) 1	0 / 1 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Reproductive system and breast disorders			
Breast pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Scrotal oedema subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Scrotal pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Vaginal discharge subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	4 / 9 (44.44%) 6	1 / 2 (50.00%) 1	0 / 1 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	5 / 9 (55.56%) 10	1 / 2 (50.00%) 1	0 / 1 (0.00%) 0
Dyspnoea exertional			

subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	3 / 9 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Hiccups			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Pleuritic pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Pneumothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	2 / 9 (22.22%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Bradyphrenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ammonia increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Blood glucose increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Carbon dioxide decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymph node palpable			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urine protein/creatinine ratio increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Weight increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Injury, poisoning and procedural complications			
Ankle fracture subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 2	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Vascular access complication subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Vascular access site occlusion			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bell's palsy			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Disturbance in attention			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Secondary cerebellar degeneration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 9 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Lymph node pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eyelid rash			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Periorbital oedema subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Vitreous floaters subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	1 / 1 (100.00%) 1
Abdominal pain subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	1 / 2 (50.00%) 1	0 / 1 (0.00%) 0
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 2 (50.00%) 1	0 / 1 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Anal haemorrhage subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Anorectal discomfort subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Aphthous ulcer subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Ascites			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 9 (11.11%)	2 / 2 (100.00%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Diarrhoea			
subjects affected / exposed	2 / 9 (22.22%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	8	1	0
Diverticulum			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Odynophagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Autoimmune dermatitis subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 2	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hyperkeratosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Nail disorder subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	5 / 9 (55.56%) 11	2 / 2 (100.00%) 2	0 / 1 (0.00%) 0
Psoriasis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Rash			

subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Rash erythematous			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 9 (11.11%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Rash papular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Micturition urgency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Nephritis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Urinary incontinence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Thyroiditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 9 (33.33%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	10	0	0
Arthritis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	2 / 9 (22.22%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Weight bearing difficulty			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Cryptosporidiosis infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Erysipelas			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Peritonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Rash pustular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	2 / 9 (22.22%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	2 / 2 (100.00%)	0 / 1 (0.00%)
occurrences (all)	1	3	0

Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Wound infection subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	1 / 2 (50.00%) 1	0 / 1 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hypernatraemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hypoalbuminaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Hypophosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 November 2016	Removal of Part 1B. Addition of Part 2D, 2E, 3C and Part 2A cohort dose -1
04 April 2017	Addition of Parts 4, 5, 6, and 7. Update of inclusion and exclusion criteria to include the new parts and clarify the maximum number of prior treatments allowed
11 December 2017	Addition of Part 8
22 June 2018	Incorporates DRibble vaccine (DPV-001) as a new combination with BMS 986178 in Part 9

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported