



## Clinical trial results:

### A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies.

#### Summary

EudraCT number	2016-004989-25
Trial protocol	ES BE
Global end of trial date	09 November 2021

#### Results information

Result version number	v2 (current)
This version publication date	24 December 2022
First version publication date	15 December 2022
Version creation reason	<ul style="list-style-type: none"><li>• Correction of full data set</li></ul> Changes made to align with changes made to ClinicalTrials.gov results summary.

#### Trial information

##### Trial identification

Sponsor protocol code	INCAGN 1876-201
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##### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff Drive, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.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	09 November 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	09 November 2021
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The purpose of this study is to determine the safety, tolerability, and efficacy of INCAGN01876 when given in combination with immune therapies in subjects with advanced or metastatic malignancies.

Protection of trial subjects:

This study was to be performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and conducted in adherence to the study Protocol, Good Clinical Practices as defined in Title 21 of the United States Code of Federal Regulations Parts 50, 54 56, 312, and Part 11 as well as International Council for Harmonisation Good Clinical Practice (ICH GCP) consolidated guidelines (E6) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 April 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 13
Country: Number of subjects enrolled	Belgium: 27
Country: Number of subjects enrolled	Spain: 21
Country: Number of subjects enrolled	United States: 84
Worldwide total number of subjects	145
EEA total number of subjects	48

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)	94
From 65 to 84 years	51
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Participants were enrolled at 32 study centers in Australia, Belgium, Spain, and the United States.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W

Arm description:

Participants received INCAGN01876 1.0 milligrams per kilogram (mg/kg) administered intravenously (IV) every 2 weeks (Q2W) in combination with nivolumab 240 mg administered IV Q2W.

Arm type	Experimental
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

10 mg/mL concentrate for solution for intravenous infusion

<b>Arm title</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W
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Arm description:

Participants received INCAGN01876 3.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

10 mg/mL concentrate for solution for intravenous infusion

Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	
<b>Arm title</b>	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W
Arm description:	
Participants received INCAGN01876 5.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	
<b>Arm title</b>	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Arm description:	
Participants received INCAGN01876 10.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	
<b>Arm title</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Arm description:	
Participants received INCAGN01876 1.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.	
Arm type	Experimental

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	
<b>Arm title</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Arm description:	
Participants received INCAGN01876 3.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	
<b>Arm title</b>	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Arm description:	
Participants received INCAGN01876 5.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL

<b>Arm title</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
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**Arm description:**

Participants received INCAGN01876 1.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV every 6 weeks (Q6W).

Arm type	Experimental
Investigational medicinal product name	ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

5 mg/mL concentrate for solution for intravenous infusion

Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL

<b>Arm title</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
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**Arm description:**

Participants received INCAGN01876 3.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.

Arm type	Experimental
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL

Investigational medicinal product name	ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

5 mg/mL concentrate for solution for intravenous infusion

<b>Arm title</b>	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
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**Arm description:**

Participants received INCAGN01876 5.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.

Arm type	Experimental
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Investigational medicinal product name	ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
5 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	
<b>Arm title</b>	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab
Arm description:	
Participants received INCAGN01876 1.0 mg/kg administered IV Q2W in combination with nivolumab 3 mg/kg administered IV Q2W and ipilimumab 1 mg/kg administered IV Q6W.	
Arm type	Experimental
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	
Investigational medicinal product name	ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
5 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/mL concentrate for solution for intravenous infusion	
<b>Arm title</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg
Arm description:	
Participants with programmed cell death protein/programmed cell death ligand 1 (PD-1/PD-L1) relapsed melanoma (RM) received INCAGN01876 300 mg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.	
Arm type	Experimental



Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	
Investigational medicinal product name	ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
5 mg/mL concentrate for solution for intravenous infusion	
<b>Arm title</b>	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg
Arm description:	
Participants with gastric cancer (GC) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	
<b>Arm title</b>	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg
Arm description:	
Participants with squamous cell carcinoma of the head and neck (SCCHN) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL

<b>Arm title</b>	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
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**Arm description:**

Participants with cervical cancer (CC) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

10 mg/mL concentrate for solution for intravenous infusion

Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL

<b>Arm title</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg
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**Arm description:**

Participants with PD-1/PD-L1 relapsed melanoma received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

10 mg/mL concentrate for solution for intravenous infusion

Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

**Dosage and administration details:**

50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL

<b>Arm title</b>	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg
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**Arm description:**

Participants with gastric cancer, squamous cell carcinoma of the head and neck, cervical cancer, or PD-1/PD-L1 relapsed melanoma who had tumor lesions that were amenable to percutaneous biopsy received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Arm type	Experimental
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Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/mL concentrate for solution for intravenous infusion	
Investigational medicinal product name	INCAGN01876
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL	

<b>Number of subjects in period 1</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W
Started	4	4	5
Completed	0	1	0
Not completed	4	3	5
Adverse event, serious fatal	2	2	4
Consent withdrawn by subject	1	-	-
Progressive Disease	-	-	-
Study terminated by the sponsor	-	-	-
Safety follow-up no longer necessary	1	-	-
Survival follow-up no longer necessary	-	-	1
Lost to follow-up	-	1	-
Started new treatment	-	-	-

<b>Number of subjects in period 1</b>	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Started	4	5	4
Completed	0	0	0
Not completed	4	5	4
Adverse event, serious fatal	3	4	4
Consent withdrawn by subject	1	1	-
Progressive Disease	-	-	-
Study terminated by the sponsor	-	-	-
Safety follow-up no longer necessary	-	-	-

Survival follow-up no longer necessary	-	-	-
Lost to follow-up	-	-	-
Started new treatment	-	-	-

<b>Number of subjects in period 1</b>	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Started	4	4	8
Completed	1	0	0
Not completed	3	4	8
Adverse event, serious fatal	3	4	5
Consent withdrawn by subject	-	-	2
Progressive Disease	-	-	-
Study terminated by the sponsor	-	-	-
Safety follow-up no longer necessary	-	-	-
Survival follow-up no longer necessary	-	-	-
Lost to follow-up	-	-	1
Started new treatment	-	-	-

<b>Number of subjects in period 1</b>	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg
Started	3	6	8
Completed	0	0	0
Not completed	3	6	8
Adverse event, serious fatal	2	6	6
Consent withdrawn by subject	1	-	1
Progressive Disease	-	-	-
Study terminated by the sponsor	-	-	-
Safety follow-up no longer necessary	-	-	-
Survival follow-up no longer necessary	-	-	-
Lost to follow-up	-	-	1
Started new treatment	-	-	-

<b>Number of subjects in period 1</b>	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Started	16	46	18
Completed	0	12	2
Not completed	16	34	16
Adverse event, serious fatal	12	25	11
Consent withdrawn by subject	3	3	2

Progressive Disease	-	1	-
Study terminated by the sponsor	-	4	-
Safety follow-up no longer necessary	-	-	-
Survival follow-up no longer necessary	-	-	-
Lost to follow-up	1	1	2
Started new treatment	-	-	1

<b>Number of subjects in period 1</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg
Started	4	2
Completed	0	0
Not completed	4	2
Adverse event, serious fatal	3	2
Consent withdrawn by subject	1	-
Progressive Disease	-	-
Study terminated by the sponsor	-	-
Safety follow-up no longer necessary	-	-
Survival follow-up no longer necessary	-	-
Lost to follow-up	-	-
Started new treatment	-	-

## Baseline characteristics

### Reporting groups

Reporting group title	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 1.0 milligrams per kilogram (mg/kg) administered intravenously (IV) every 2 weeks (Q2W) in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 3.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 5.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 10.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 1.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.	
Reporting group title	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 3.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.	
Reporting group title	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 5.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.	
Reporting group title	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Reporting group description: Participants received INCAGN01876 1.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV every 6 weeks (Q6W).	
Reporting group title	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Reporting group description: Participants received INCAGN01876 3.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.	
Reporting group title	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Reporting group description: Participants received INCAGN01876 5.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.	
Reporting group title	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab
Reporting group description: Participants received INCAGN01876 1.0 mg/kg administered IV Q2W in combination with nivolumab 3 mg/kg administered IV Q2W and ipilimumab 1 mg/kg administered IV Q6W.	
Reporting group title	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab

## Reporting group description:

Participants with programmed cell death protein/programmed cell death ligand 1 (PD-1/PD-L1) relapsed melanoma (RM) received INCAGN01876 300 mg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.

Reporting group title	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with gastric cancer (GC) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with squamous cell carcinoma of the head and neck (SCCHN) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with cervical cancer (CC) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with PD-1/PD-L1 relapsed melanoma received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with gastric cancer, squamous cell carcinoma of the head and neck, cervical cancer, or PD-1/PD-L1 relapsed melanoma who had tumor lesions that were amenable to percutaneous biopsy received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group values	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W
Number of subjects	4	4	5
Age categorical			
Units: Subjects			
Adults (18-64 years)	4	1	4
From 65-84 years	0	3	1
Age Continuous			
Units: Years			
arithmetic mean	51.3	59.8	48.0
standard deviation	± 7.37	± 14.03	± 18.23
Sex: Female, Male			
Units:			
Female	2	2	5
Male	2	2	0
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
White/Caucasian	2	3	4
Black or African American	1	0	1
Asian	0	0	0
American Indian or Alaska Native	0	0	0

Native Hawaiiin or Other Pacific Islander	0	0	0
Other: Captured as "Other"	1	1	0
Other: Zimbabwean	0	0	0
Other: Mexican	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	1	1
Not Hispanic or Latino	3	3	4
Unknown or Not Reported	0	0	0

<b>Reporting group values</b>	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Number of subjects	4	5	4
Age categorical			
Units: Subjects			
Adults (18-64 years)	3	2	3
From 65-84 years	1	3	1
Age Continuous			
Units: Years			
arithmetic mean	62.3	60.8	62.5
standard deviation	± 7.04	± 12.40	± 16.36
Sex: Female, Male			
Units:			
Female	3	3	3
Male	1	2	1
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
White/Caucasian	3	2	3
Black or African American	1	0	1
Asian	0	2	0
American Indian or Alaska Native	0	0	0
Native Hawaiiin or Other Pacific Islander	0	0	0
Other: Captured as "Other"	0	1	0
Other: Zimbabwean	0	0	0
Other: Mexican	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	4	4	4
Unknown or Not Reported	0	0	0

<b>Reporting group values</b>	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Number of subjects	4	4	8



Age categorical			
Units: Subjects			
Adults (18-64 years)	2	1	5
From 65-84 years	2	3	3
Age Continuous			
Units: Years			
arithmetic mean	63.0	61.5	61.8
standard deviation	± 9.90	± 11.73	± 7.70
Sex: Female, Male			
Units:			
Female	3	3	5
Male	1	1	3
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
White/Caucasian	4	3	6
Black or African American	0	0	0
Asian	0	1	1
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other: Captured as "Other"	0	0	0
Other: Zimbabwean	0	0	0
Other: Mexican	0	0	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	4	4	7
Unknown or Not Reported	0	0	0

<b>Reporting group values</b>	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg
Number of subjects	3	6	8
Age categorical			
Units: Subjects			
Adults (18-64 years)	1	4	1
From 65-84 years	2	2	7
Age Continuous			
Units: Years			
arithmetic mean	67.7	58.5	69.1
standard deviation	± 4.16	± 11.24	± 9.46
Sex: Female, Male			
Units:			
Female	1	2	3
Male	2	4	5
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
White/Caucasian	3	6	8
Black or African American	0	0	0

Asian	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiin or Other Pacific Islander	0	0	0
Other: Captured as "Other"	0	0	0
Other: Zimbabwean	0	0	0
Other: Mexican	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	6	8
Unknown or Not Reported	0	0	0

Reporting group values	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Number of subjects	16	46	18
Age categorical			
Units: Subjects			
Adults (18-64 years)	10	30	18
From 65-84 years	6	16	0
Age Continuous			
Units: Years			
arithmetic mean	59.1	60.5	48.6
standard deviation	± 10.48	± 9.46	± 9.43
Sex: Female, Male			
Units:			
Female	5	8	18
Male	11	38	0
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
White/Caucasian	14	45	16
Black or African American	1	1	1
Asian	0	0	1
American Indian or Alaska Native	0	0	0
Native Hawaiin or Other Pacific Islander	0	0	0
Other: Captured as "Other"	0	0	0
Other: Zimbabwean	1	0	0
Other: Mexican	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	1	1
Not Hispanic or Latino	14	43	17
Unknown or Not Reported	1	2	0

Reporting group values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg	Total
Number of subjects	4	2	145

Age categorical			
Units: Subjects			
Adults (18-64 years)	3	2	94
From 65-84 years	1	0	51
Age Continuous			
Units: Years			
arithmetic mean	54.3	42.0	
standard deviation	± 9.29	± 16.97	-
Sex: Female, Male			
Units:			
Female	1	1	68
Male	3	1	77
Race/Ethnicity, Customized			
Ethnicity			
Units: Subjects			
White/Caucasian	4	2	128
Black or African American	0	0	7
Asian	0	0	5
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other: Captured as "Other"	0	0	3
Other: Zimbabwean	0	0	1
Other: Mexican	0	0	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	8
Not Hispanic or Latino	4	2	134
Unknown or Not Reported	0	0	3

## End points

### End points reporting groups

Reporting group title	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 1.0 milligrams per kilogram (mg/kg) administered intravenously (IV) every 2 weeks (Q2W) in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 3.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 5.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 10.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 1.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.	
Reporting group title	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 3.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.	
Reporting group title	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Reporting group description: Participants received INCAGN01876 5.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.	
Reporting group title	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Reporting group description: Participants received INCAGN01876 1.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV every 6 weeks (Q6W).	
Reporting group title	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Reporting group description: Participants received INCAGN01876 3.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.	
Reporting group title	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Reporting group description: Participants received INCAGN01876 5.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.	
Reporting group title	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab
Reporting group description: Participants received INCAGN01876 1.0 mg/kg administered IV Q2W in combination with nivolumab 3 mg/kg administered IV Q2W and ipilimumab 1 mg/kg administered IV Q6W.	

Reporting group title	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg
Reporting group description: Participants with programmed cell death protein/programmed cell death ligand 1 (PD-1/PD-L1) relapsed melanoma (RM) received INCAGN01876 300 mg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.	
Reporting group title	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg
Reporting group description: Participants with gastric cancer (GC) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg
Reporting group description: Participants with squamous cell carcinoma of the head and neck (SCCHN) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Reporting group description: Participants with cervical cancer (CC) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg
Reporting group description: Participants with PD-1/PD-L1 relapsed melanoma received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	
Reporting group title	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg
Reporting group description: Participants with gastric cancer, squamous cell carcinoma of the head and neck, cervical cancer, or PD-1/PD-L1 relapsed melanoma who had tumor lesions that were amenable to percutaneous biopsy received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.	

### **Primary: Phase 1: Number of participants with any treatment-emergent adverse event (TEAE)**

End point title	Phase 1: Number of participants with any treatment-emergent adverse event (TEAE) <sup>[1][2]</sup>
End point description: An adverse event (AE) was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, that occurred after a participant provided informed consent. Abnormal laboratory values or test results occurring after informed consent constituted AEs only if they induced clinical signs or symptoms, were considered clinically meaningful, required therapy (e.g., hematologic abnormality that required transfusion), or required changes in the study drug(s). A TEAE was defined as any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study medication.	
End point type	Primary
End point timeframe: up to approximately 27.4 months	

#### **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: Statistical analysis was not conducted.

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

Justification: Statistical analysis was not conducted.

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: participants	4	4	5	4

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	4	4
Units: participants	5	4	4	4

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	3	6	
Units: participants	7	3	6	

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2: Objective response rate (ORR) per RECIST v1.1

End point title	Phase 2: Objective response rate (ORR) per RECIST v1.1 <sup>[3][4]</sup>
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End point description:

ORR was defined as the percentage of participants with a best overall response of confirmed complete response (CR) or partial response (PR), determined by investigator assessment of radiographic disease assessments per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 (v1.1). CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 millimeters (mm). PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions.

End point type	Primary
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End point timeframe:

up to approximately 44.7 months

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: Statistical analysis was not conducted.

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

Justification: Statistical analysis was not conducted.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	16	46	18
Units: Percentage of Participants				
number (not applicable)	0.0	0.0	23.9	16.7

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Percentage of Participants				
number (not applicable)	0.0	0.0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: ORR per RECIST v1.1

End point title	Phase 1: ORR per RECIST v1.1 <sup>[5]</sup>
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End point description:

ORR was defined as the percentage of participants with a best overall response of unconfirmed CR or PR, determined by investigator assessment of radiographic disease assessments per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

[5] - 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: Statistical analysis was not conducted.

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: Percentage of Participants				
number (not applicable)	25.0	0.0	20.0	0.0

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	4	4
Units: Percentage of Participants				
number (not applicable)	0.0	0.0	25.0	25.0

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	3	6	
Units: Percentage of Participants				
number (not applicable)	12.5	0.0	0.0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: ORR per modified RECIST (mRECIST) v1.1

End point title	Phase 1: ORR per modified RECIST (mRECIST) v1.1 <sup>[6]</sup>
End point description:	
ORR was defined as the percentage of participants with a best overall response of unconfirmed CR or PR, determined by investigator assessment of radiographic disease assessments per mRECIST v1.1. The response of target lesions was evaluated from the percentage change in the sum of the diameters of the viable portions (portions enhanced during the arterial phase). CR: Disappearance of any intratumoral arterial enhancement during in target lesions, disappearance of all non-target lesions, and no appearance of any new lesions. PR: $\geq 30\%$ of the sum of the diameters of viable portions (enhancement on arterial phase) of target lesions taking as reference the Baseline sum, no new lesions, and no progression of non-target lesions.	
End point type	Secondary



End point timeframe:

up to approximately 44.7 months

Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: Percentage of Participants				
number (not applicable)	25.0	0.0	20.0	0.0

End point values	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	4	4
Units: Percentage of Participants				
number (not applicable)	0.0	0.0	25.0	25.0

End point values	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	3	6	
Units: Percentage of Participants				
number (not applicable)	12.5	0.0	0.0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: ORR per mRECIST v1.1

End point title	Phase 2: ORR per mRECIST v1.1 <sup>[7]</sup>
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End point description:

ORR was defined as the percentage of participants with a best overall response of confirmed CR or PR, determined by investigator assessment of radiographic disease assessments per mRECIST v1.1. The

response of target lesions was evaluated from the percentage change in the sum of the diameters of the viable portions (portions enhanced during the arterial phase). CR: Disappearance of any intratumoral arterial enhancement during in target lesions, disappearance of all non-target lesions, and no appearance of any new lesions. PR:  $\geq 30\%$  of the sum of the diameters of viable portions (enhancement on arterial phase) of target lesions taking as reference the Baseline sum, no new lesions, and no progression of non-target lesions.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

[7] - 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: Statistical analysis was not conducted.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	16	46	18
Units: Percentage of Participants				
number (not applicable)	0.0	0.0	26.1	16.7

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Percentage of Participants				
number (not applicable)	0.0	0.0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: Duration of response (DOR) per RECIST v1.1

End point title	Phase 1: Duration of response (DOR) per RECIST v1.1 <sup>[8]</sup>
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End point description:

DOR was defined as the time from the first overall response contributing to an unconfirmed objective response (CR or PR) to the earlier of the participant's death from any cause or the first assessment of PD, determined by investigator assessment of radiographic disease assessment per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to  $< 10$  mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. -9999/9999 = not estimable; too few participants had disease progression or died. Only those participants with a response of CR or PR were analyzed.

End point type	Secondary				
End point timeframe:					
up to approximately 44.7 months					
Notes:					
[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Statistical analysis was not conducted.					
End point values	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W	
	Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
	Number of subjects analysed	1	0 <sup>[9]</sup>	1	0 <sup>[10]</sup>
	Units: Days				
	median (confidence interval 95%)	9999 (-9999 to 9999)	( to )	573.0 (-9999 to 9999)	( to )

Notes:

[9] - Only those participants with a response of CR or PR were analyzed.

[10] - Only those participants with a response of CR or PR were analyzed.

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[11]</sup>	0 <sup>[12]</sup>	1	1
Units: Days				
median (confidence interval 95%)	( to )	( to )	876.0 (-9999 to 9999)	9999 (-9999 to 9999)

Notes:

[11] - Only those participants with a response of CR or PR were analyzed.

[12] - Only those participants with a response of CR or PR were analyzed.

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	0 <sup>[13]</sup>	0 <sup>[14]</sup>	
Units: Days				
median (confidence interval 95%)	281.0 (-9999 to 9999)	( to )	( to )	

Notes:

[13] - Only those participants with a response of CR or PR were analyzed.

[14] - Only those participants with a response of CR or PR were analyzed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: DOR per RECIST v1.1

End point title	Phase 2: DOR per RECIST v1.1 <sup>[15]</sup>
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#### End point description:

DOR was defined as the time from the first overall response contributing to a confirmed objective response (CR or PR) to the earlier of the participant's death from any cause or the first assessment of PD, determined by investigator assessment of radiographic disease assessment per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. -9999/9999 = not estimable; too few participants had disease progression or died. Only those participants with a response of CR or PR were analyzed.

End point type	Secondary
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#### End point timeframe:

up to approximately 44.7 months

#### Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[16]</sup>	0 <sup>[17]</sup>	11	3
Units: Days				
median (confidence interval 95%)	( to )	( to )	9999 (118.0 to 9999)	120.0 (113.0 to 9999)

#### Notes:

[16] - Only those participants with a response of CR or PR were analyzed.

[17] - Only those participants with a response of CR or PR were analyzed.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 <sup>[18]</sup>	0 <sup>[19]</sup>		
Units: Days				
median (confidence interval 95%)	( to )	( to )		

#### Notes:

[18] - Only those participants with a response of CR or PR were analyzed.

[19] - Only those participants with a response of CR or PR were analyzed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: DOR per mRECIST v1.1

End point title	Phase 1: DOR per mRECIST v1.1 <sup>[20]</sup>
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#### End point description:

DOR was defined as the time from the first unconfirmed overall response contributing to an unconfirmed

objective response (CR or PR) to the earlier of the participant's death from any cause or the first confirmed assessment of PD, determined by investigator assessment of radiographic disease assessment per mRECIST v1.1. The response of target lesions was evaluated from the percentage change in the sum of the diameters of the viable portions (portions enhanced during the arterial phase). CR: Disappearance of any intratumoral arterial enhancement during in target lesions, disappearance of all non-target lesions, and no appearance of any new lesions. PR:  $\geq 30\%$  of the sum of the diameters of viable portions (enhancement on arterial phase) of target lesions taking as reference the Baseline sum, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. -9999/9999 = not estimable.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

[20] - 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: Statistical analysis was not conducted.

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0 <sup>[21]</sup>	1	0 <sup>[22]</sup>
Units: Days				
median (confidence interval 95%)	9999 (-9999 to 9999)	( to )	9999 (-9999 to 9999)	( to )

Notes:

[21] - Only those participants with a response of CR or PR were analyzed

[22] - Only those participants with a response of CR or PR were analyzed

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[23]</sup>	0 <sup>[24]</sup>	1	1
Units: Days				
median (confidence interval 95%)	( to )	( to )	876.0 (-9999 to 9999)	9999 (-9999 to 9999)

Notes:

[23] - Only those participants with a response of CR or PR were analyzed

[24] - Only those participants with a response of CR or PR were analyzed

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	0 <sup>[25]</sup>	0 <sup>[26]</sup>	
Units: Days				
median (confidence interval 95%)	9999 (-9999 to 9999)	( to )	( to )	

Notes:

[25] - Only those participants with a response of CR or PR were analyzed

[26] - Only those participants with a response of CR or PR were analyzed

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase 2: DOR per mRECIST v1.1

End point title	Phase 2: DOR per mRECIST v1.1 <sup>[27]</sup>
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End point description:

DOR was defined as the time from the first overall response contributing to a confirmed objective response (CR or PR) to the earlier of the participant's death from any cause or the first assessment of PD, determined by investigator assessment of radiographic disease assessment per mRECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. -9999/9999 = not estimable; too few participants had disease progression or died. Only those participants with a response of CR or PR were analyzed.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[28]</sup>	0 <sup>[29]</sup>	12	3
Units: Days				
median (confidence interval 95%)	( to )	( to )	9999 (-9999 to 9999)	9999 (113.0 to 9999)

Notes:

[28] - Only those participants with a response of CR or PR were analyzed.

[29] - Only those participants with a response of CR or PR were analyzed.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 <sup>[30]</sup>	0 <sup>[31]</sup>		
Units: Days				
median (confidence interval 95%)	( to )	( to )		

Notes:

[30] - Only those participants with a response of CR or PR were analyzed.

[31] - Only those participants with a response of CR or PR were analyzed.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase 1: Disease control rate (DCR) per RECIST v1.1

End point title	Phase 1: Disease control rate (DCR) per RECIST v1.1 <sup>[32]</sup>
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End point description:

DCR was defined as the percentage of participants with a best overall response of unconfirmed CR, unconfirmed PR, or stable disease (SD;  $\geq 49$  days), determined by investigator assessment of radiographic disease assessments per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to  $< 10$  mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. SD: no change in target lesions to qualify for CR, PR, or PD.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

[32] - 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: Statistical analysis was not conducted.

End point values	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: Percentage of Participants				
number (not applicable)	25.0	50.0	20.0	50.0

End point values	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	4	4
Units: Percentage of Participants				
number (not applicable)	0.0	25.0	50.0	25.0

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	3	6	
Units: Percentage of Participants				
number (not applicable)	50.0	0.0	0.0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: DCR per RECIST v1.1

End point title	Phase 2: DCR per RECIST v1.1 <sup>[33]</sup>
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End point description:

DCR was defined as the percentage of participants with a best overall response of confirmed CR, confirmed PR, or SD ( $\geq 49$  days), determined by investigator assessment of radiographic disease assessments per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to  $< 10$  mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. SD: no change in target lesions to qualify for CR, PR, or PD.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

[33] - 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: Statistical analysis was not conducted.

<b>End point values</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	16	46	18
Units: Percentage of Participants				
number (not applicable)	37.5	56.3	54.3	55.6

<b>End point values</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876	Phase 2 Biopsy: INCAGN01876		
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	300 mg + nivolumab 240 mg	300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Percentage of Participants				
number (not applicable)	50.0	50.0		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase 1: DCR per mRECIST v1.1

End point title	Phase 1: DCR per mRECIST v1.1 <sup>[34]</sup>
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End point description:

DCR was defined as the percentage of participants with a best overall response of unconfirmed CR, unconfirmed PR, or stable disease (SD; ≥49 days), determined by investigator assessment of radiographic disease assessments per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. SD: no change in target lesions to qualify for CR, PR, or PD.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: Percentage of Participants				
number (not applicable)	25.0	50.0	20.0	50.0

End point values	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	4	4
Units: Percentage of Participants				

number (not applicable)	0.0	25.0	50.0	25.0
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End point values	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	3	6	
Units: Percentage of Participants				
number (not applicable)	50.0	0.0	0.0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: DCR per mRECIST v1.1

End point title	Phase 2: DCR per mRECIST v1.1 <sup>[35]</sup>
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End point description:

DCR was defined as the percentage of participants with a best overall response of confirmed CR, confirmed PR, or SD ( $\geq 49$  days), determined by investigator assessment of radiographic disease assessments per mRECIST v1.1. The response of target lesions was evaluated from the percentage change in the sum of the diameters of the viable portions (portions enhanced during the arterial phase). CR: Disappearance of any intratumoral arterial enhancement during in target lesions, disappearance of all non-target lesions, and no appearance of any new lesions. PR:  $\geq 30\%$  of the sum of the diameters of viable portions (enhancement on arterial phase) of target lesions taking as reference the Baseline sum, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. SD: no change in target lesions to qualify for CR, PR, or PD.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	16	46	18
Units: Percentage of Participants				
number (not applicable)	37.5	56.3	56.5	55.6

<b>End point values</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Percentage of Participants				
number (not applicable)	50.0	50.0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: Duration of disease control per RECIST v1.1

End point title	Phase 1: Duration of disease control per RECIST v1.1 <sup>[36]</sup>
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End point description:

Duration of disease control (CR, PR, and SD [ $\geq 49$  days]) was measured from the start of treatment until PD or death from any cause, if occurring sooner than progression, determined by investigator assessment of radiographic disease per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to  $< 10$  mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. SD: no change in target lesions to qualify for CR, PR, or PD. - 9999/9999 = not estimable; too few participants had disease progression or died. Only those participants with a response of SD, CR, or PR were analyzed.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

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

Justification: Statistical analysis was not conducted.

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	1	2
Units: Days				
arithmetic mean (confidence interval 95%)	9999 (-9999 to 9999)	9999 (89.0 to 9999)	624.0 (-9999 to 9999)	76.0 (-9999 to 9999)

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1
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	mg Q2W	mg Q2W	mg Q2W	mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[37]</sup>	1	2	1
Units: Days				
arithmetic mean (confidence interval 95%)	( to )	167.0 (-9999 to 9999)	668.5 (125.0 to 9999)	9999 (-9999 to 9999)

Notes:

[37] - Only those participants with a response of SD, CR, or PR were analyzed.

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	0 <sup>[38]</sup>	0 <sup>[39]</sup>	
Units: Days				
arithmetic mean (confidence interval 95%)	250.5 (110.0 to 9999)	( to )	( to )	

Notes:

[38] - Only those participants with a response of SD, CR, or PR were analyzed.

[39] - Only those participants with a response of SD, CR, or PR were analyzed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: Duration of disease control per RECIST v1.1

End point title	Phase 2: Duration of disease control per RECIST v1.1 <sup>[40]</sup>
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End point description:

Duration of disease control (CR, PR, and SD [ $\geq 49$  days]) was measured from the start of treatment until PD or death from any cause, if occurring sooner than progression, determined by investigator assessment of radiographic disease per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to  $< 10$  mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. SD: no change in target lesions to qualify for CR, PR, or PD. - 9999/9999 = not estimable; too few participants had disease progression or died. Only those participants with a response of SD, CR, or PR were analyzed.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	9	25	10
Units: Days				
median (confidence interval 95%)	218.0 (106.0 to 9999)	109.0 (63.0 to 9999)	253.0 (156.0 to 9999)	168.0 (71.0 to 9999)

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: Days				
median (confidence interval 95%)	206.5 (118.0 to 9999)	109.0 (-9999 to 9999)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: Duration of disease control per mRECIST v1.1

End point title	Phase 1: Duration of disease control per mRECIST v1.1 <sup>[41]</sup>
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End point description:

Duration of disease control (CR, PR, and SD [ $\geq 49$  days]) was measured from the start of treatment until PD or death from any cause, if occurring sooner than progression, determined by investigator assessment of radiographic disease per RECIST v1.1. The response of target lesions was evaluated from the percentage change in the sum of the diameters of the viable portions (portions enhanced during the arterial phase). CR: Disappearance of any intratumoral arterial enhancement during in target lesions, disappearance of all non-target lesions, and no appearance of any new lesions. PR:  $\geq 30\%$  of the sum of the diameters of viable portions (enhancement on arterial phase) of target lesions taking as reference the Baseline sum, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. SD: no change in target lesions to qualify for CR, PR, or PD. -9999/9999 = not estimable.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

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

Justification: Statistical analysis was not conducted.

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	1	2
Units: Days				
arithmetic mean (confidence interval 95%)	9999 (-9999 to 9999)	9999 (-9999 to 9999)	9999 (-9999 to 9999)	76.0 (-9999 to 9999)

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 <sup>[42]</sup>	1	2	1
Units: Days				
arithmetic mean (confidence interval 95%)	( to )	9999 (-9999 to 9999)	668.5 (125.0 to 9999)	9999 (-9999 to 9999)

Notes:

[42] - Only those participants with a response of SD, CR, or PR were analyzed.

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	0 <sup>[43]</sup>	0 <sup>[44]</sup>	
Units: Days				
arithmetic mean (confidence interval 95%)	9999 (134.0 to 9999)	( to )	( to )	

Notes:

[43] - Only those participants with a response of SD, CR, or PR were analyzed.

[44] - Only those participants with a response of SD, CR, or PR were analyzed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: Duration of disease control per mRECIST v1.1

End point title	Phase 2: Duration of disease control per mRECIST v1.1 <sup>[45]</sup>
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End point description:

Duration of disease control (CR, PR, and SD [ $\geq 49$  days]) was measured from the start of treatment until PD or death from any cause, if occurring sooner than progression, determined by investigator assessment of radiographic disease per RECIST v1.1. The response of target lesions was evaluated from the percentage change in the sum of the diameters of the viable portions (portions enhanced during the arterial phase). CR: Disappearance of any intratumoral arterial enhancement during in target lesions, disappearance of all non-target lesions, and no appearance of any new lesions. PR:  $\geq 30\%$  of the sum of the diameters of viable portions (enhancement on arterial phase) of target lesions taking as reference the Baseline sum, no new lesions, and no progression of non-target lesions. PD: progression of a target

or non-target lesion or presence of a new lesion. SD: no change in target lesions to qualify for CR, PR, or PD. -9999/9999 = not estimable.

End point type	Secondary
End point timeframe:	
up to approximately 44.7 months	

Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	9	26	10
Units: Days				
median (confidence interval 95%)	218.0 (133.0 to 9999)	168.0 (63.0 to 9999)	9999 (202.0 to 9999)	9999 (137.0 to 9999)

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: Days				
median (confidence interval 95%)	9999 (118.0 to 9999)	9999 (-9999 to 9999)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: Progression-free survival (PFS) per RECIST v1.1

End point title	Phase 1: Progression-free survival (PFS) per RECIST v1.1 <sup>[46]</sup>
End point description:	
According to RECIST 1.1, PFS was defined as the length of time between the Baseline visit (Day 1) and the earlier of death or the first assessment of PD, as determined by investigator assessment of objective radiographic disease assessments. -9999/9999 = not estimable; too few participants had disease progression or died.	
End point type	Secondary
End point timeframe:	
up to approximately 44.7 months	

Notes:

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

Justification: Statistical analysis was not conducted.

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: Days				
median (confidence interval 95%)	52.5 (48.0 to 9999)	72.0 (53.0 to 9999)	53.0 (9.0 to 9999)	64.0 (48.0 to 9999)

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	4	4
Units: Days				
median (confidence interval 95%)	47.5 (29.0 to 9999)	60.0 (50.0 to 9999)	88.5 (44.0 to 9999)	41.0 (15.0 to 9999)

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	3	6	
Units: Days				
median (confidence interval 95%)	110.0 (53.0 to 276.0)	56.0 (53.0 to 9999)	54.5 (21.0 to 9999)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: PFS per RECIST v1.1

End point title	Phase 2: PFS per RECIST v1.1 <sup>[47]</sup>
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End point description:

According to RECIST 1.1, PFS was defined as the length of time between the Baseline visit (Day 1) and



the earlier of death or the first assessment of PD, as determined by investigator assessment of objective radiographic disease assessments. -9999/9999 = not estimable; too few participants had disease progression or died.

End point type	Secondary
End point timeframe:	
up to approximately 44.7 months	

Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	16	46	18
Units: Days				
median (confidence interval 95%)	57.0 (20.0 to 218.0)	75.0 (45.0 to 120.0)	115.0 (59.0 to 174.0)	102.0 (51.0 to 225.0)

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Days				
median (confidence interval 95%)	87.0 (52.0 to 9999)	64.5 (20.0 to 9999)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: PFS per mRECIST v1.1

End point title	Phase 1: PFS per mRECIST v1.1 <sup>[48]</sup>
End point description:	
According to mRECIST 1.1, PFS was defined as the length of time between the Baseline visit (Day 1) and the earlier of the participant's death or the first confirmed assessment of PD, as determined by investigator assessment of objective radiographic disease assessments. The response of target lesions was evaluated from the percentage change in the sum of the diameters of the viable portions (portions enhanced during the arterial phase). -9999/9999 = not estimable; too few participants had disease progression or died.	
End point type	Secondary
End point timeframe:	
up to approximately 44.7 months	

Notes:

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

Justification: Statistical analysis was not conducted.

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: Days				
median (confidence interval 95%)	66.0 (48.0 to 9999)	9999 (55.0 to 9999)	116.0 (64.0 to 9999)	88.0 (76.0 to 9999)

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	4	4
Units: Days				
median (confidence interval 95%)	57.0 (29.0 to 9999)	9999 (100.0 to 9999)	98.0 (52.0 to 9999)	9999 (97.0 to 9999)

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	3	6	
Units: Days				
median (confidence interval 95%)	134.0 (53.0 to 9999)	128.0 (56.0 to 9999)	9999 (46.0 to 9999)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: PFS per mRECIST v1.1

End point title	Phase 2: PFS per mRECIST v1.1 <sup>[49]</sup>
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End point description:

According to mRECIST 1.1, PFS was defined as the length of time between the Baseline visit (Day 1)

and the earlier of the participant's death or the first confirmed assessment of PD, as determined by investigator assessment of objective radiographic disease assessments. The response of target lesions was evaluated from the percentage change in the sum of the diameters of the viable portions (portions enhanced during the arterial phase). -9999/9999 = not estimable; too few participants had disease progression or died.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

Notes:

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

Justification: Statistical analysis was not conducted.

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	16	46	18
Units: Days				
median (confidence interval 95%)	85.0 (20.0 to 218.0)	105.0 (63.0 to 9999)	235.0 (129.0 to 9999)	168.0 (51.0 to 9999)

End point values	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Days				
median (confidence interval 95%)	118.0 (52.0 to 9999)	9999 (20.0 to 9999)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: Overall survival

End point title	Phase 1: Overall survival <sup>[50]</sup>
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End point description:

Overall survival was defined as the interval between the Baseline visit (Day 1) and the date of death due to any cause. -9999/9999 = not estimable; too few participants had disease progression or died.

End point type	Secondary
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End point timeframe:

up to approximately 44.7 months

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: Statistical analysis was not conducted.

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: Days				
median (confidence interval 95%)	9999 (76.0 to 9999)	9999 (55.0 to 9999)	253.0 (77.0 to 9999)	100.0 (76.0 to 9999)

<b>End point values</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	4	4
Units: Days				
median (confidence interval 95%)	289.5 (170.0 to 9999)	266.5 (100.0 to 9999)	588.0 (424.0 to 9999)	200.0 (97.0 to 9999)

<b>End point values</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	3	6	
Units: Days				
median (confidence interval 95%)	425.0 (110.0 to 9999)	627.0 (128.0 to 9999)	229.5 (46.0 to 9999)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: Overall survival

End point title	Phase 2: Overall survival <sup>[51]</sup>
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End point description:

Overall survival was defined as the interval between the Baseline visit (Day 1) and the date of death due

to any cause. -9999/9999 = not estimable; too few participants had disease progression or died.

End point type	Secondary
End point timeframe:	
up to approximately 44.7 months	

Notes:

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

Justification: Statistical analysis was not conducted.

<b>End point values</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	16	46	18
Units: Days				
median (confidence interval 95%)	290.5 (20.0 to 9999)	179.0 (75.0 to 404.0)	491.0 (344.0 to 9999)	492.0 (92.0 to 733.0)

<b>End point values</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Days				
median (confidence interval 95%)	485.0 (52.0 to 9999)	264.0 (20.0 to 9999)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2: Number of Participants with any TEAE

End point title	Phase 2: Number of Participants with any TEAE <sup>[52]</sup>
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End point description:

An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, that occurred after a participant provided informed consent. Abnormal laboratory values or test results occurring after informed consent constituted AEs only if they induced clinical signs or symptoms, were considered clinically meaningful, required therapy (e.g., hematologic abnormality that required transfusion), or required changes in the study drug(s). A TEAE was defined as any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study medication.

End point type	Secondary
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End point timeframe:

up to approximately 27.4 months

Notes:

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

Justification: Statistical analysis was not conducted.

<b>End point values</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	16	46	18
Units: Participants	8	16	45	18

<b>End point values</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Participants	4	2		

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

up to approximately 27.4 months

Adverse event reporting additional description:

TEAEs (AEs reported for the first time or the worsening of pre-existing events after the first dose of study medication) were monitored for at least 60 days after the last dose of study treatment or until the start of new anticancer therapy (up to 27.4 months). All-Cause Mortality was monitored for the duration of the study (up to 44.7 months).

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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### Reporting groups

Reporting group title	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W
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Reporting group description:

Participants received INCAGN01876 3.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W
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Reporting group description:

Participants received INCAGN01876 1.0 milligrams per kilogram (mg/kg) administered intravenously (IV) every 2 weeks (Q2W) in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W
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Reporting group description:

Participants received INCAGN01876 5.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W
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Reporting group description:

Participants received INCAGN01876 10.0 mg/kg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W
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Reporting group description:

Participants received INCAGN01876 1.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.

Reporting group title	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W
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Reporting group description:

Participants received INCAGN01876 1.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.

Reporting group title	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
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Reporting group description:

Participants received INCAGN01876 1.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV every 6 weeks (Q6W).

Reporting group title	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W
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Reporting group description:

Participants received INCAGN01876 5.0 mg/kg administered IV Q2W for a total of 2 doses as run-in, followed by nivolumab 240 mg administered IV Q2W starting at Cycle 3.

Reporting group title	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg
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## Reporting group description:

Participants received INCAGN01876 3.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.

Reporting group title	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
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## Reporting group description:

Participants received INCAGN01876 5.0 mg/kg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.

Reporting group title	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab
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## Reporting group description:

Participants received INCAGN01876 1.0 mg/kg administered IV Q2W in combination with nivolumab 3 mg/kg administered IV Q2W and ipilimumab 1 mg/kg administered IV Q6W.

Reporting group title	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg
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## Reporting group description:

Participants with programmed cell death protein/programmed cell death ligand 1 (PD-1/PD-L1) relapsed melanoma (RM) received INCAGN01876 300 mg administered IV Q2W in combination with ipilimumab 1 mg/kg administered IV Q6W.

Reporting group title	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with gastric cancer (GC) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with squamous cell carcinoma of the head and neck (SCCHN) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with cervical cancer (CC) received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with PD-1/PD-L1 relapsed melanoma received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg
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## Reporting group description:

Participants with gastric cancer, squamous cell carcinoma of the head and neck, cervical cancer, or PD-1/PD-L1 relapsed melanoma who had tumor lesions that were amenable to percutaneous biopsy received INCAGN01876 300 mg administered IV Q2W in combination with nivolumab 240 mg administered IV Q2W.

Reporting group title	Total
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## Reporting group description:

Total

<b>Serious adverse events</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	2 / 4 (50.00%)	3 / 5 (60.00%)
number of deaths (all causes)	2	2	4
number of deaths resulting from	2	0	0



adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer metastatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (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
Bronchial obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
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 / 5 (0.00%)
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%)	2 / 5 (40.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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			
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral artery embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (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
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (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 haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (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
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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			
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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			
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 disorder			



subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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			
Arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis staphylococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
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 klebsiella			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
number of deaths (all causes)	3	4	4
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer metastatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Tumour haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (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
Obstructive airways disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	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
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
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 artery aneurysm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			



subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral artery embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	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
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (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
Dysphagia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
Cholecystitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
Arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis staphylococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal bacteraemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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	1 / 4 (25.00%)	0 / 5 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
Diabetic ketoacidosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
<b>Serious adverse events</b>			
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	2 / 4 (50.00%)	3 / 8 (37.50%)
number of deaths (all causes)	4	3	5
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer metastatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Cancer pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Tumour haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Death			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Facial pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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%)	1 / 4 (25.00%)	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
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Bronchial obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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

Obstructive airways disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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%)	0 / 4 (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
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (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 artery aneurysm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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%)	0 / 4 (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 failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Product issues			

Device occlusion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Spinal fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Toxicity to various agents			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Wound complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Atrioventricular block			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Myocarditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (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			
Cerebral artery embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Headache			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Ischaemic stroke			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Myoclonus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Spinal cord compression			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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%)	1 / 4 (25.00%)	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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Abdominal pain upper			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (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 / 4 (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 intestine perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (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
Oesophageal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (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
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Cholecystitis acute			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Arthritis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Myopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Endocarditis staphylococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 urinary tract infection			



subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pneumonia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Pneumonia klebsiella			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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 / 1	0 / 0	0 / 0
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Failure to thrive			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (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

<b>Serious adverse events</b>	Phase 1:	Phase 1:	Phase 2 PD-1/PD-L1
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	INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	INCAGN01876 + Nivolumab + Ipilimumab	RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	3 / 8 (37.50%)
number of deaths (all causes)	2	6	6
number of deaths resulting from adverse events	0	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer metastatic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	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 / 1	0 / 0
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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	0 / 3 (0.00%)	0 / 6 (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
Tumour haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Chest pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Facial pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Bronchial obstruction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Obstructive airways disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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 artery aneurysm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	1 / 6 (16.67%)	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
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Product issues			
Device occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Spinal fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Toxicity to various agents			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Wound complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Atrioventricular block			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Myocarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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
Nervous system disorders			
Cerebral artery embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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

Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Ischaemic stroke			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Myoclonus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Spinal cord compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Syncope			



subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (33.33%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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	1 / 3 (33.33%)	0 / 6 (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
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 intestine perforation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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
Oesophageal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Cholecystitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Myopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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			
Appendicitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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

Cellulitis				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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	
Endocarditis staphylococcal				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 urinary tract infection				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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 klebsiella				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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	
Pseudomonal bacteraemia				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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	
Pyelonephritis acute				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 tract infection				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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 respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Wound infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Failure to thrive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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
Hyperglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (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 / 3 (0.00%)	0 / 6 (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

<b>Serious adverse events</b>	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 16 (68.75%)	19 / 46 (41.30%)	10 / 18 (55.56%)
number of deaths (all causes)	12	25	11
number of deaths resulting from adverse events	3	7	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer metastatic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Malignant neoplasm progression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tumour pain			

subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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			
Chest pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (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
Death			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Facial pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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 physical health deterioration			
subjects affected / exposed	2 / 16 (12.50%)	0 / 46 (0.00%)	0 / 18 (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
Performance status decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (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
Peripheral swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Hypoxia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
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 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
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 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0



Pneumothorax			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
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 artery aneurysm			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	3 / 16 (18.75%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (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
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (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
Product issues			
Device occlusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Spinal fracture			

subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Cardiac arrest			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Myocarditis			

subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (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
Pericardial effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral artery embolism			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Headache			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Myoclonus			

subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
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 / 16 (12.50%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (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
Ascites			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			

subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (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
Intestinal obstruction			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
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 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal obstruction			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 16 (12.50%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
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			
Nephrolithiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
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			
Hypothyroidism			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
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 pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myopathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Endocarditis staphylococcal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Escherichia urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
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	2 / 16 (12.50%)	3 / 46 (6.52%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal bacteraemia			

subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (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
Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
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			
Diabetic ketoacidosis			



subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
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 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg	Total
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	1 / 2 (50.00%)	68 / 145 (46.90%)
number of deaths (all causes)	3	2	98
number of deaths resulting from adverse events	0	0	18
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer metastatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cancer pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Tumour haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Facial pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchial obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Obstructive airways disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
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 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery aneurysm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
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 / 2 (0.00%)	4 / 145 (2.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			

Device occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Atrial fibrillation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Cerebral artery embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	4 / 145 (2.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
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 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
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 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
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			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
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			
Arthritis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
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 pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis staphylococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Escherichia urinary tract infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	8 / 145 (5.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia klebsiella			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
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 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 5.0 mg/kg Q2W + nivolumab 240 mg Q2W
Total subjects affected by non-serious adverse events subjects affected / exposed	4 / 4 (100.00%)	4 / 4 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Squamous cell carcinoma of skin subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Vascular disorders Embolism subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1
Hot flush subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1
Hypertension subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Orthostatic hypotension subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Peripheral coldness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 5 (40.00%)
occurrences (all)	0	1	2
Inadequate analgesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Medical device site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Seasonal allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast hyperplasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Menopausal symptoms			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Penile pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus genital			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal dryness			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoxia			



subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Depression subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	1 / 4 (25.00%) 2	0 / 5 (0.00%) 0
Amylase increased subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	1 / 4 (25.00%) 3	0 / 5 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 2	1 / 4 (25.00%) 1	0 / 5 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
C-reactive protein increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Clostridium test positive			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Corneal abrasion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seroma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Synovial rupture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Allodynia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Somnolence			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	1	2	1
Increased tendency to bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retinal tear			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			

subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Diaphragmatic hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dyschezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Gastritis			



subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Oesophageal stenosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Varices oesophageal			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	2	0	2
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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 / 5 (0.00%)
occurrences (all)	0	0	0

Bladder irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 5 (40.00%)
occurrences (all)	0	1	2
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cestode infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Helminthic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Hordeolum			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Infected cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Mucosal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Omphalitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Penile infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pneumococcal sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Pyelonephritis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Scrotal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Iron deficiency			



subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Phase 1: INCAGN01876 10.0 mg/kg Q2W + nivolumab 240 mg Q2W	Phase 1: INCAGN01876 1.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W, then nivolumab 240 mg Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	5 / 5 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (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 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Inadequate analgesia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Medical device site pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Reproductive system and breast disorders			
Breast hyperplasia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Menopausal symptoms subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Pelvic discomfort subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Penile pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Pruritus genital subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Vulvovaginal dryness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Atelectasis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Cough			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Troponin I increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Injury, poisoning and procedural complications			
Corneal abrasion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Seroma subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Skin laceration subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Synovial rupture subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Pericardial effusion			



subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Allodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	2 / 5 (40.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Dizziness postural			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (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 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Increased tendency to bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lymph node pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinal tear			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Diaphragmatic hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Eructation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oesophageal stenosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Varices oesophageal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Hepatobiliary disorders			

Cholelithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	3 / 5 (60.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	3 / 5 (60.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bladder irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Ureteric obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Urinary tract obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	1 / 4 (25.00%) 1
Flank pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Muscle disorder subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Muscular weakness			



subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cestode infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Helminthic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Oesophageal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Omphalitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Penile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Pneumococcal sepsis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypomagnesaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Polydipsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 5.0 mg/kg Q2W, then nivolumab 240 mg Q2W	Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	4 / 4 (100.00%)	7 / 8 (87.50%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Vascular disorders			
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Peripheral coldness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (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%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Inadequate analgesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Medical device site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	3
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Immune system disorders			

Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	2 / 8 (25.00%) 2
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Reproductive system and breast disorders			
Breast hyperplasia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Menopausal symptoms subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	0 / 8 (0.00%) 0
Pelvic discomfort subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Penile pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Pruritus genital subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Vulvovaginal dryness			



subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	3 / 8 (37.50%)
occurrences (all)	0	2	3
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Heart rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Protein total decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Troponin I increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1
Injury, poisoning and procedural complications			
Corneal abrasion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1
Seroma subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Skin laceration			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Synovial rupture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Allodynia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Balance disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Dizziness postural			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tension headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1

Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Lymph node pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1
Neutropenia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (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 / 8 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1
Eye disorders Cataract subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Eye pruritus subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Iridocyclitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Retinal tear subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1
Vision blurred			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	2	1	2
Diaphragmatic hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2



Duodenal ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Eructation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	4 / 8 (50.00%)
occurrences (all)	2	0	6
Oesophageal stenosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Varices oesophageal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	4 / 8 (50.00%)
occurrences (all)	2	0	5
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	3 / 8 (37.50%)
occurrences (all)	1	0	3
Rash			

subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	1	2	2
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bladder irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	3 / 4 (75.00%)	1 / 8 (12.50%)
occurrences (all)	0	3	1
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	2 / 8 (25.00%)
occurrences (all)	1	2	2
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Tendon pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cestode infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Helminthic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	2	0	2
Oesophageal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Omphalitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Penile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumococcal sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pyelonephritis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pyelonephritis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Scrotal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	2 / 8 (25.00%)
occurrences (all)	0	5	7

Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Dehydration			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Folate deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			



subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Malnutrition			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

<b>Non-serious adverse events</b>	Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W	Phase 1: INCAGN01876 + Nivolumab + Ipilimumab	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + ipilimumab 1 mg/kg
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Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Squamous cell carcinoma of skin subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 8 (0.00%) 0
Vascular disorders Embolism subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Orthostatic hypotension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Peripheral coldness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 8 (0.00%) 0
Catheter site pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	6 / 8 (75.00%)
occurrences (all)	1	1	6
Inadequate analgesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Medical device site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Pain			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1
Pyrexia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	1 / 8 (12.50%) 1
Immune system disorders Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Reproductive system and breast disorders Breast hyperplasia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Menopausal symptoms subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Pelvic discomfort subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Pelvic pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Penile pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pruritus genital			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	3 / 8 (37.50%)
occurrences (all)	0	1	3
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Oropharyngeal pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Corneal abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Procedural pain			



subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Seroma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Synovial rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Allodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Dizziness postural			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tension headache			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Tremor subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	3 / 6 (50.00%) 3	0 / 8 (0.00%) 0
Increased tendency to bruise subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Lymph node pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 8 (0.00%) 0
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Eye disorders			
Cataract subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Eye pruritus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Iridocyclitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Retinal tear			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1

Diaphragmatic hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Duodenal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	3
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Nausea			
subjects affected / exposed	2 / 3 (66.67%)	0 / 6 (0.00%)	3 / 8 (37.50%)
occurrences (all)	3	0	3
Oesophageal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Varices oesophageal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	3 / 8 (37.50%)
occurrences (all)	1	1	4
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 8 (25.00%)
occurrences (all)	0	1	3
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Bladder irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Renal impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ureteric obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			



Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Muscle disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Tendon pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Infections and infestations			
Cestode infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Helminthic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Influenza			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Oesophageal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Omphalitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Penile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumococcal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Scrotal infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	2
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	1 / 8 (12.50%)
occurrences (all)	1	3	1
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Folate deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Polydipsia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0

Vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1

<b>Non-serious adverse events</b>	Phase 2 GC: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 SCCHN: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	15 / 16 (93.75%)	43 / 46 (93.48%)	18 / 18 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Squamous cell carcinoma of skin subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Vascular disorders Embolism subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 46 (2.17%) 1	0 / 18 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	4 / 46 (8.70%) 5	3 / 18 (16.67%) 3
Hypotension subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	3 / 46 (6.52%) 3	1 / 18 (5.56%) 1
Orthostatic hypotension			

subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 16 (6.25%)	7 / 46 (15.22%)	2 / 18 (11.11%)
occurrences (all)	2	10	2
Catheter site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Chest discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	5 / 16 (31.25%)	15 / 46 (32.61%)	5 / 18 (27.78%)
occurrences (all)	6	22	5
Inadequate analgesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Medical device site pain			

subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 16 (6.25%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	3 / 16 (18.75%)	3 / 46 (6.52%)	2 / 18 (11.11%)
occurrences (all)	3	3	2
Pain			
subjects affected / exposed	0 / 16 (0.00%)	3 / 46 (6.52%)	0 / 18 (0.00%)
occurrences (all)	0	4	0
Peripheral swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 16 (18.75%)	7 / 46 (15.22%)	0 / 18 (0.00%)
occurrences (all)	3	8	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast hyperplasia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Breast pain			



subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Intermenstrual bleeding			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Menopausal symptoms			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pelvic pain			
subjects affected / exposed	2 / 16 (12.50%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Penile pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pruritus genital			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 16 (12.50%)	12 / 46 (26.09%)	2 / 18 (11.11%)
occurrences (all)	2	14	3
Dyspnoea			
subjects affected / exposed	5 / 16 (31.25%)	5 / 46 (10.87%)	1 / 18 (5.56%)
occurrences (all)	5	5	1
Dysphonia			

subjects affected / exposed	0 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Haemoptysis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Hypoxia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	3 / 46 (6.52%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Pneumonitis			
subjects affected / exposed	1 / 16 (6.25%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Productive cough			
subjects affected / exposed	0 / 16 (0.00%)	6 / 46 (13.04%)	0 / 18 (0.00%)
occurrences (all)	0	6	0
Pulmonary embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Respiratory disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	2 / 16 (12.50%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			

Anxiety			
subjects affected / exposed	3 / 16 (18.75%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	3	1	0
Confusional state			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	2 / 16 (12.50%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Insomnia			
subjects affected / exposed	2 / 16 (12.50%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	2	2	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 16 (6.25%)	2 / 46 (4.35%)	1 / 18 (5.56%)
occurrences (all)	1	5	1
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Clostridium test positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 16 (0.00%)	3 / 46 (6.52%)	0 / 18 (0.00%)
occurrences (all)	0	11	0
Lipase increased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Neutrophil count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Protein total decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	3 / 16 (18.75%)	4 / 46 (8.70%)	2 / 18 (11.11%)
occurrences (all)	3	5	2
Injury, poisoning and procedural			

complications			
Corneal abrasion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Seroma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	1 / 16 (6.25%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Synovial rupture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	3 / 46 (6.52%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Pericardial effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Tachycardia			

subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 46 (0.00%) 0	1 / 18 (5.56%) 1
Nervous system disorders			
Allodynia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 16 (12.50%)	3 / 46 (6.52%)	1 / 18 (5.56%)
occurrences (all)	2	3	1
Dizziness postural			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Encephalopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 16 (12.50%)	4 / 46 (8.70%)	1 / 18 (5.56%)
occurrences (all)	4	5	1
Lethargy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Sciatica			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tension headache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 16 (6.25%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 16 (18.75%)	7 / 46 (15.22%)	5 / 18 (27.78%)
occurrences (all)	3	12	6
Increased tendency to bruise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Tinnitus			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 46 (2.17%) 1	0 / 18 (0.00%) 0
Eye disorders			
Cataract			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Conjunctival haemorrhage			
subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Eye pruritus			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Iridocyclitis			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Retinal tear			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Vision blurred			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	2 / 46 (4.35%) 2	1 / 18 (5.56%) 1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Abdominal pain			
subjects affected / exposed occurrences (all)	3 / 16 (18.75%) 3	1 / 46 (2.17%) 1	6 / 18 (33.33%) 6
Abdominal distension			
subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Abdominal pain upper			
subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Abdominal pain lower			



subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	4 / 16 (25.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	6	0	1
Constipation			
subjects affected / exposed	3 / 16 (18.75%)	8 / 46 (17.39%)	2 / 18 (11.11%)
occurrences (all)	3	8	2
Diaphragmatic hernia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	6 / 16 (37.50%)	8 / 46 (17.39%)	8 / 18 (44.44%)
occurrences (all)	7	11	8
Dry mouth			
subjects affected / exposed	1 / 16 (6.25%)	2 / 46 (4.35%)	1 / 18 (5.56%)
occurrences (all)	1	3	1
Duodenal ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	2 / 16 (12.50%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	2	2	0
Dysphagia			
subjects affected / exposed	2 / 16 (12.50%)	4 / 46 (8.70%)	0 / 18 (0.00%)
occurrences (all)	2	4	0
Eructation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Flatulence			

subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 16 (12.50%)	0 / 46 (0.00%)	2 / 18 (11.11%)
occurrences (all)	2	0	2
Haemorrhoids			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	6 / 16 (37.50%)	7 / 46 (15.22%)	5 / 18 (27.78%)
occurrences (all)	7	8	5
Oesophageal stenosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Varices oesophageal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 16 (25.00%)	5 / 46 (10.87%)	2 / 18 (11.11%)
occurrences (all)	4	8	3
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			

subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Hyperhidrosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ingrowing nail			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 16 (18.75%)	9 / 46 (19.57%)	7 / 18 (38.89%)
occurrences (all)	5	9	7
Rash			
subjects affected / exposed	3 / 16 (18.75%)	6 / 46 (13.04%)	1 / 18 (5.56%)
occurrences (all)	3	8	1
Rash erythematous			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Rash maculo-papular			
subjects affected / exposed	0 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Rash pruritic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Bladder irritation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Chromaturia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	1 / 16 (6.25%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ureteric obstruction			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Urinary tract obstruction subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Endocrine disorders			
Hyperthyroidism subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	7 / 46 (15.22%) 9	1 / 18 (5.56%) 1
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	3 / 16 (18.75%) 3	7 / 46 (15.22%) 7	1 / 18 (5.56%) 1
Back pain subjects affected / exposed occurrences (all)	4 / 16 (25.00%) 4	2 / 46 (4.35%) 2	1 / 18 (5.56%) 1
Flank pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	1 / 18 (5.56%) 1
Groin pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Muscle disorder subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 46 (2.17%) 1	0 / 18 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 46 (2.17%) 1	1 / 18 (5.56%) 1
Myalgia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 46 (0.00%) 0	0 / 18 (0.00%) 0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 16 (0.00%)	3 / 46 (6.52%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Neck pain			
subjects affected / exposed	0 / 16 (0.00%)	3 / 46 (6.52%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Pain in extremity			
subjects affected / exposed	1 / 16 (6.25%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Tendon pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cestode infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Diverticulitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	0 / 16 (0.00%)	3 / 46 (6.52%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Fungal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	3
Fungal skin infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences (all)	0	1	1

Helminthic infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Infected cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Mucosal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Omphalitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 16 (0.00%)	3 / 46 (6.52%)	1 / 18 (5.56%)
occurrences (all)	0	3	1
Penile infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pneumococcal sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	1	1	0

Pyelonephritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis acute			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Scrotal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	6 / 46 (13.04%)	1 / 18 (5.56%)
occurrences (all)	0	8	2
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	4 / 18 (22.22%)
occurrences (all)	0	0	6
Urosepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	7 / 16 (43.75%)	3 / 46 (6.52%)	1 / 18 (5.56%)
occurrences (all)	7	3	1
Dehydration			



subjects affected / exposed	0 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Folate deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	3 / 46 (6.52%)	2 / 18 (11.11%)
occurrences (all)	0	4	2
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Hypernatraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 46 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Hypokalaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Hypomagnesaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 46 (4.35%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			

subjects affected / exposed	1 / 16 (6.25%)	3 / 46 (6.52%)	0 / 18 (0.00%)
occurrences (all)	1	3	0
Iron deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 46 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 16 (0.00%)	1 / 46 (2.17%)	0 / 18 (0.00%)
occurrences (all)	0	1	0

<b>Non-serious adverse events</b>	Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg	Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg	Total
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	2 / 2 (100.00%)	139 / 145 (95.86%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2

Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	8 / 145 (5.52%)
occurrences (all)	0	0	9
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	6 / 145 (4.14%)
occurrences (all)	0	0	6
Orthostatic hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Peripheral coldness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	13 / 145 (8.97%)
occurrences (all)	0	0	17
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	40 / 145 (27.59%)
occurrences (all)	1	0	48
Inadequate analgesia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Medical device site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Non-cardiac chest pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	4 / 145 (2.76%)
occurrences (all)	1	0	4
Oedema peripheral			
subjects affected / exposed	2 / 4 (50.00%)	1 / 2 (50.00%)	17 / 145 (11.72%)
occurrences (all)	2	1	17
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	6 / 145 (4.14%)
occurrences (all)	0	0	8
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	15 / 145 (10.34%)
occurrences (all)	0	0	17
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1

Seasonal allergy subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Reproductive system and breast disorders			
Breast hyperplasia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Breast pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Intermenstrual bleeding subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Menopausal symptoms subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Pelvic discomfort subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Pelvic pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	3 / 145 (2.07%) 3
Penile pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Pruritus genital subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Vulvovaginal dryness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Respiratory, thoracic and mediastinal disorders			
Atelectasis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1	1 / 145 (0.69%) 1
Cough			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	27 / 145 (18.62%)
occurrences (all)	0	0	31
Dyspnoea			
subjects affected / exposed	2 / 4 (50.00%)	0 / 2 (0.00%)	23 / 145 (15.86%)
occurrences (all)	2	0	23
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Haemoptysis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	1	0	3
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	4 / 145 (2.76%)
occurrences (all)	0	0	4
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	8 / 145 (5.52%)
occurrences (all)	0	1	8
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	8 / 145 (5.52%)
occurrences (all)	0	0	8
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Respiratory disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Rhinorrhoea			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	2 / 145 (1.38%) 2
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	2 / 145 (1.38%) 2
Psychiatric disorders			
Anxiety			
subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0	6 / 145 (4.14%) 6
Confusional state			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1	3 / 145 (2.07%) 3
Depression			
subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0	3 / 145 (2.07%) 4
Insomnia			
subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0	7 / 145 (4.83%) 7
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0	5 / 145 (3.45%) 6
Amylase increased			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	5 / 145 (3.45%) 8
Aspartate aminotransferase increased			
subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0	7 / 145 (4.83%) 8
Blood alkaline phosphatase increased			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	2 / 145 (1.38%) 2
Blood bilirubin increased			
subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0	2 / 145 (1.38%) 2
Blood cholesterol increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	7 / 145 (4.83%)
occurrences (all)	0	0	10
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Clostridium test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Heart rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Hepatic enzyme increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	11
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Protein total decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1



Troponin I increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Weight decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	11 / 145 (7.59%) 12
Injury, poisoning and procedural complications			
Corneal abrasion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Fall subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	3 / 145 (2.07%) 3
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0	2 / 145 (1.38%) 4
Procedural pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	2 / 145 (1.38%) 2
Seroma subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Skin abrasion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Skin laceration subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	2 / 145 (1.38%) 3
Synovial rupture subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	3 / 145 (2.07%) 3
Pericardial effusion			

subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	1 / 145 (0.69%)
occurrences (all)	0	1	1
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	5 / 145 (3.45%)
occurrences (all)	0	1	5
Nervous system disorders			
Allodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	13 / 145 (8.97%)
occurrences (all)	0	1	14
Dizziness postural			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	13 / 145 (8.97%)
occurrences (all)	0	0	16
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	4 / 145 (2.76%)
occurrences (all)	0	0	4

Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Tension headache			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	1	0	1
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	3
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	25 / 145 (17.24%)
occurrences (all)	0	0	32
Increased tendency to bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Lymph node pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Neutropenia			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	3 / 145 (2.07%) 3
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Iridocyclitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	1 / 145 (0.69%)
occurrences (all)	0	1	1
Retinal tear			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	13 / 145 (8.97%)
occurrences (all)	0	0	13
Abdominal distension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	5 / 145 (3.45%)
occurrences (all)	0	0	5
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Anorectal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	9 / 145 (6.21%)
occurrences (all)	0	0	11
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	21 / 145 (14.48%)
occurrences (all)	0	0	22
Diaphragmatic hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	27 / 145 (18.62%)
occurrences (all)	0	0	31
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	7 / 145 (4.83%)
occurrences (all)	0	0	8
Duodenal ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Dyschezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	5 / 145 (3.45%)
occurrences (all)	0	0	5
Dysphagia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	11 / 145 (7.59%)
occurrences (all)	0	0	11
Eructation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	4 / 145 (2.76%)
occurrences (all)	0	0	6
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	5 / 145 (3.45%)
occurrences (all)	0	0	5
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	2 / 2 (100.00%)	35 / 145 (24.14%)
occurrences (all)	1	2	40
Oesophageal stenosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	5 / 145 (3.45%)
occurrences (all)	0	0	5
Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Varices oesophageal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	21 / 145 (14.48%)
occurrences (all)	0	1	26
Hepatobiliary disorders			

Cholelithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Ingrowing nail			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	2 / 4 (50.00%)	0 / 2 (0.00%)	36 / 145 (24.83%)
occurrences (all)	3	0	41
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	22 / 145 (15.17%)
occurrences (all)	0	0	26
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Rash maculo-papular			

subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	6 / 145 (4.14%)
occurrences (all)	2	0	7
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	3
Bladder irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Chromaturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	1	0	3
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Renal impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1



Ureteric obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Urinary tract obstruction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	2 / 145 (1.38%) 2
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	11 / 145 (7.59%) 13
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 2	0 / 2 (0.00%) 0	21 / 145 (14.48%) 22
Back pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	16 / 145 (11.03%) 16
Flank pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Groin pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Muscle disorder subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	1 / 145 (0.69%) 1
Muscle spasms subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0	2 / 145 (1.38%) 2
Muscular weakness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	4 / 145 (2.76%)
occurrences (all)	0	0	4
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 2 (50.00%)	8 / 145 (5.52%)
occurrences (all)	1	1	8
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	4 / 145 (2.76%)
occurrences (all)	0	0	4
Pain in extremity			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	8 / 145 (5.52%)
occurrences (all)	1	0	8
Tendon pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Infections and infestations			
Cestode infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Diverticulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	1 / 145 (0.69%)
occurrences (all)	0	1	1
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	4

Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	2
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Helminthic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Infected cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Mucosal infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	1 / 145 (0.69%)
occurrences (all)	0	1	1
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	7 / 145 (4.83%)
occurrences (all)	0	0	11
Oesophageal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	1 / 145 (0.69%)
occurrences (all)	0	1	1
Omphalitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	5 / 145 (3.45%)
occurrences (all)	0	0	5
Penile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1

Pneumococcal sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Pyelonephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Pyelonephritis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Scrotal infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	1	0	1
Skin infection			
subjects affected / exposed	2 / 4 (50.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	3	0	4
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	13 / 145 (8.97%)
occurrences (all)	0	0	17
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	9 / 145 (6.21%)
occurrences (all)	0	0	19
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	22 / 145 (15.17%)
occurrences (all)	0	1	22
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	5 / 145 (3.45%)
occurrences (all)	0	0	6
Folate deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	6 / 145 (4.14%)
occurrences (all)	0	0	7
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	4 / 145 (2.76%)
occurrences (all)	0	0	4
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	4 / 145 (2.76%)
occurrences (all)	0	1	4
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	5 / 145 (3.45%)
occurrences (all)	0	0	5
Hypomagnesaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	7 / 145 (4.83%)
occurrences (all)	0	0	7
Iron deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	2 / 145 (1.38%)
occurrences (all)	0	0	2
Polydipsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Vitamin B12 deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 145 (0.69%)
occurrences (all)	0	0	1
Vitamin D deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	3 / 145 (2.07%)
occurrences (all)	0	0	3

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 June 2017	The primary purpose of this amendment was to update the sponsor name and address to Incyte Biosciences International Sàrl.
22 August 2017	The primary purpose of this amendment was to address clinical trial application review comments from the Belgian and Spanish regulatory agencies.
24 October 2018	The primary purpose of this amendment was (1) to introduce mandatory pretreatment biopsy sample collection for all participants to be enrolled in the Phase 2 portion of the study, and (2) to explore the combination therapy of INCAGN01876 with nivolumab in participants with programmed cell death protein (PD-1) refractory squamous cell carcinoma of head and neck (SCCHN).
22 January 2021	The primary purpose of this amendment was to provide guidance for the management of ongoing participants, as enrollment was complete and sufficient data had been collected for primary and secondary endpoint analysis.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported