# 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 | • Correction of full data set<br>Changes made to align with changes made to ClinicalTrials.gov results summary. |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | INCAGN 1876-201 |

### 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 |
| **Arm title** | 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

| | |
|---|---|
| **Arm title** | Phase 1: INCAGN01876 3.0 mg/kg Q2W + nivolumab 240 mg Q2W |

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

| | |
|---|---|
| **Arm title** | 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

| | |
|---|---|
| **Arm title** | 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

| | |
|---|---|
| **Arm title** | 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

| | |
|---|---|
| **Arm title** | 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

| | |
|---|---|
| **Arm title** | 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 | |

| | |
|---|---|
| **Arm title** | Phase 1: INCAGN01876 1.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W |
| 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 | |
| **Arm title** | Phase 1: INCAGN01876 3.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W |
| 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 | |
| **Arm title** | Phase 1: INCAGN01876 5.0 mg/kg Q2W + ipilimumab 1 mg/kg Q6W |
| 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 |

| | |
|---|---|
| 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

| | |
|---|---|
| **Arm title** | 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

| | |
|---|---|
| **Arm title** | 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

| | |
|---|---|
| **Arm title** | 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

| | |
|---|---|
| **Arm title** | 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:<br>50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL | |

| | |
|---|---|
| **Arm title** | Phase 2 CC: INCAGN01876 300 mg + nivolumab 240 mg |
| Arm description:<br>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:<br>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:<br>50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL | |
| **Arm title** | Phase 2 PD-1/PD-L1 RM: INCAGN01876 300 mg + nivolumab 240 mg |
| Arm description:<br>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:<br>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:<br>50 mg of INCAGN01876 in 5 milliliters (mL) at a concentration of 10 mg/mL | |
| **Arm title** | Phase 2 Biopsy: INCAGN01876 300 mg + nivolumab 240 mg |
| Arm description:<br>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 |

| | |
|---|---|
| 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

| **Number of subjects in period 1** | 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 | - | - | - |

| **Number of subjects in period 1** | 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 | - | - | - |

| **Number of subjects in period 1** | 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 | - | - | - |

| **Number of subjects in period 1** | 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 | - | - | - |

| **Number of subjects in period 1** | 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 |

| **Number of subjects in period 1** | 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 | - | - |

| **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.

| **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<br>Units: Subjects | | | |
| Adults (18-64 years) | 4 | 1 | 4 |
| From 65-84 years | 0 | 3 | 1 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 51.3 | 59.8 | 48.0 |
| standard deviation | ± 7.37 | ± 14.03 | ± 18.23 |
| Sex: Female, Male<br>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 Hawaiin 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 |

| **Reporting group values** | 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 Hawaiin 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 |

| **Reporting group values** | 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<br>Units: Subjects | | | |
| Adults (18-64 years) | 2 | 1 | 5 |
| From 65-84 years | 2 | 3 | 3 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 63.0 | 61.5 | 61.8 |
| standard deviation | ± 9.90 | ± 11.73 | ± 7.70 |
| Sex: Female, Male<br>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 Hawaiin 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)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 1 |
| Not Hispanic or Latino | 4 | 4 | 7 |
| Unknown or Not Reported | 0 | 0 | 0 |

| **Reporting group values** | 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<br>Units: Subjects | | | |
| Adults (18-64 years) | 1 | 4 | 1 |
| From 65-84 years | 2 | 2 | 7 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 67.7 | 58.5 | 69.1 |
| standard deviation | ± 4.16 | ± 11.24 | ± 9.46 |
| Sex: Female, Male<br>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<br>Units: Subjects | | | |
| Adults (18-64 years) | 3 | 2 | 94 |
| From 65-84 years | 1 | 0 | 51 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 54.3 | 42.0 | |
| standard deviation | ± 9.29 | ± 16.97 | - |
| Sex: Female, Male<br>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 Hawaiin 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)<br>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)[1][2] |
|---|---|

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.

| 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: participants | 4 | 4 | 5 | 4 |

| 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: participants | 5 | 4 | 4 | 4 |

| 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: 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[3][4] |
|---|---|

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 |
|---|---|

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[5] |
|---|---|

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 |
|---|---|

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.

| 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 1: ORR per modified RECIST (mRECIST) v1.1

| End point title | Phase 1: ORR per modified RECIST (mRECIST) v1.1[6] |
|---|---|

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: ≥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[7] |
|---|---|

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: ≥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:

[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[8] |
|---|---|

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[9] | 1 | 0[10] |
| 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.

| **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 | 0[11] | 0[12] | 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.

| **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 | 1 | 0[13] | 0[14] | |
| 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[15] |
|---|---|

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 |
|---|---|

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[16] | 0[17] | 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[18] | 0[19] | | |
| 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[20] |
|---|---|

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: ≥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 |
|---|---|

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.

| **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[21] | 1 | 0[22] |
| 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

| **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 | 0[23] | 0[24] | 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

| **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 | 1 | 0[25] | 0[26] | |
| 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[27] |
|---|---|

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 |
|---|---|

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[28] | 0[29] | 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[30] | 0[31] | | |
| 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[32] |
|---|---|

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 |
|---|---|

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 |

| 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 RECIST v1.1

| End point title | Phase 2: DCR per RECIST v1.1[33] |
|---|---|

End point description:

DCR was defined as the percentage of participants with a best overall response of confirmed CR, confirmed PR, or 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 |
|---|---|

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.

| 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 | 54.3 | 55.6 |

| End point values | Phase 2 PD-1/PD-L1 RM: INCAGN01876 | Phase 2 Biopsy: INCAGN01876 | | |
|---|---|---|---|---|

| | 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[34] |
|---|---|

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 |
|---|---|

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 |

| **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[35] |
|---|---|

End point description:

DCR was defined as the percentage of participants with a best overall response of confirmed CR, confirmed PR, or SD (≥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: ≥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 |
|---|---|

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 |

| 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) | 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[36] |
|---|---|

End point description:

Duration of disease control (CR, PR, and SD [≥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 |
|---|---|

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.

| 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 | 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) |

| End point values | 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 |
|---|---|---|---|---|

| | 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[37] | 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.

| **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 | 4 | 0[38] | 0[39] | |
| 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[40] |
|---|---|

End point description:

Duration of disease control (CR, PR, and SD [≥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 |
|---|---|

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[41] |
|---|---|

End point description:

Duration of disease control (CR, PR, and SD [≥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: ≥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:

[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.

| 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 | 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) |

| 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 | 0[42] | 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.

| 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 | 4 | 0[43] | 0[44] | |
| 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[45] |
|---|---|

End point description:

Duration of disease control (CR, PR, and SD [≥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: ≥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[46] |
|---|---|

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.

| **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: 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) |

| **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: 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) |

| **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: 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[47] |
|---|---|

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[48] |
|---|---|

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.

| **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: 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) |

| **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: 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) |

| **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: 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[49] |
|---|---|

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:

[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[50] |
|---|---|

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:

[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.

| **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: 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) |

| **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: 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) |

| **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: 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[51] |
|---|---|

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.

| **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%) | 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) |

| **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%) | 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[52] |
|---|---|

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 |
|---|---|

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.

| **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: Participants | 8 | 16 | 45 | 18 |

| **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: Participants | 4 | 2 | | |

## Statistical analyses

No statistical analyses for this end point

## 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 |

## Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 24.0 |

## Reporting groups

| | |
|---|---|
| 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 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 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 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 |

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 |

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 |

| | |
|---|---|
| | 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.

| | |
|---|---|
| Reporting group title | Total |

Reporting group description:

Total

| **Serious adverse events** | 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 |

| **Serious adverse events** | 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 |

| **Serious adverse events** | 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 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 |

| **Serious adverse events** | Phase 1: | Phase 1: | Phase 2 PD-1/PD-L1 |
|---|---|---|---|

| | 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 |

| **Serious adverse events** | 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 |

| **Serious adverse events** | 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 %

| **Non-serious adverse events** | 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 | 1 / 4 (25.00%) | 0 / 4 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Embolism | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral coldness | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 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 | | | |

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

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|---|---|---|---|
| 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 | | | |

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|---|---|---|---|
| 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 |

| **Non-serious adverse events** | 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 | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **Reproductive system and breast disorders** | | | |
| Breast hyperplasia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intermenstrual bleeding | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Menopausal symptoms | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic discomfort | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Penile pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus genital | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal dryness | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **Respiratory, thoracic and mediastinal disorders** | | | |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 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 | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 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 | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Corneal abrasion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 5 (20.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Seroma | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 5 (20.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Synovial rupture | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 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 | 0 / 4 (0.00%) | 0 / 5 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 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 | | | |

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

| **Non-serious adverse events** | 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 | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (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 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intermenstrual bleeding | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Menopausal symptoms | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 4 (25.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pelvic discomfort | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Penile pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus genital | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 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 | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Protein total decreased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Troponin I increased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Injury, poisoning and procedural complications | | | |
| Corneal abrasion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Seroma | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 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 | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye pruritus | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iridocyclitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Retinal tear | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Vision blurred | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 4 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 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 |

| **Non-serious adverse events** | 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 |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events<br>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 | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 6 (16.67%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vascular disorders | | | |
| Embolism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral coldness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 6 (16.67%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 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 | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 6 (16.67%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Breast hyperplasia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intermenstrual bleeding | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Menopausal symptoms | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic discomfort | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 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 | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tremor | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 3 / 6 (50.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 6 (16.67%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 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 | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |

| **Non-serious adverse events** | 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 | 0 / 16 (0.00%) | 0 / 46 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 46 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Embolism | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 46 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 1 / 46 (2.17%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 16 (0.00%) | 0 / 46 (0.00%) | 0 / 18 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 4 / 46 (8.70%) | 3 / 18 (16.67%) |
| occurrences (all) | 1 | 5 | 3 |
| Hypotension | | | |
| subjects affected / exposed | 1 / 16 (6.25%) | 3 / 46 (6.52%) | 1 / 18 (5.56%) |
| occurrences (all) | 1 | 3 | 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 | | | |

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|---|---|---|---|
| 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 | | | |

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|---|---|---|---|
| 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 | | | |

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|---|---|---|---|
| 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 | | | |

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|---|---|---|---|
| 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 | | | |

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

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

| **Non-serious adverse events** | 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 | 1 / 4 (25.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 1 | 0 | 1 |
| Reproductive system and breast disorders | | | |
| Breast hyperplasia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Intermenstrual bleeding | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Menopausal symptoms | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Pelvic discomfort | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 3 / 145 (2.07%) |
| occurrences (all) | 0 | 0 | 3 |
| Penile pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Pruritus genital | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Vulvovaginal dryness | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 2 (50.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 1 | 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 | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 2 / 145 (1.38%) |
| occurrences (all) | 0 | 0 | 2 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 2 / 145 (1.38%) |
| occurrences (all) | 0 | 0 | 2 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 2 (0.00%) | 6 / 145 (4.14%) |
| occurrences (all) | 1 | 0 | 6 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 2 (50.00%) | 3 / 145 (2.07%) |
| occurrences (all) | 0 | 1 | 3 |
| Depression | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 2 (0.00%) | 3 / 145 (2.07%) |
| occurrences (all) | 1 | 0 | 4 |
| Insomnia | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 2 (0.00%) | 7 / 145 (4.83%) |
| occurrences (all) | 1 | 0 | 7 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 2 (0.00%) | 5 / 145 (3.45%) |
| occurrences (all) | 1 | 0 | 6 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 5 / 145 (3.45%) |
| occurrences (all) | 0 | 0 | 8 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 2 (0.00%) | 7 / 145 (4.83%) |
| occurrences (all) | 1 | 0 | 8 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 2 / 145 (1.38%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 2 (0.00%) | 2 / 145 (1.38%) |
| occurrences (all) | 1 | 0 | 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 | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 11 / 145 (7.59%) |
| occurrences (all) | 0 | 0 | 12 |
| Injury, poisoning and procedural complications | | | |
| Corneal abrasion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Fall | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 3 / 145 (2.07%) |
| occurrences (all) | 0 | 0 | 3 |
| Infusion related reaction | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 2 (0.00%) | 2 / 145 (1.38%) |
| occurrences (all) | 1 | 0 | 4 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 2 / 145 (1.38%) |
| occurrences (all) | 0 | 0 | 2 |
| Seroma | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 2 / 145 (1.38%) |
| occurrences (all) | 0 | 0 | 3 |
| Synovial rupture | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 1 / 145 (0.69%) |
| occurrences (all) | 0 | 0 | 1 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 3 / 145 (2.07%) |
| occurrences (all) | 0 | 0 | 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 | 0 / 4 (0.00%) | 0 / 2 (0.00%) | 3 / 145 (2.07%) |
| occurrences (all) | 0 | 0 | 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 | | | |

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

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported