



Clinical trial results:

A Phase 3, Randomized, Double-blind Study of BMS-986205 Combined with Nivolumab versus Nivolumab in Participants with Metastatic or Unresectable Melanoma that is Previously Untreated

Summary

| | |
|--------------------------|--|
| EudraCT number | 2017-002499-14 |
| Trial protocol | DE NL ES GB IE CZ GR PL FR Outside EU/EEA IT |
| Global end of trial date | 02 July 2020 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 04 July 2021 |
| First version publication date | 04 July 2021 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | CA017-055 |
|-----------------------|-----------|

Additional study identifiers

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

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 27 October 2020 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 02 July 2020 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess safety and tolerability of the administered treatment

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 30 November 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: 4 |
| Country: Number of subjects enrolled | New Zealand: 1 |
| Country: Number of subjects enrolled | Germany: 3 |
| Country: Number of subjects enrolled | Spain: 3 |
| Country: Number of subjects enrolled | Italy: 4 |
| Country: Number of subjects enrolled | United Kingdom: 1 |
| Country: Number of subjects enrolled | Netherlands: 1 |
| Country: Number of subjects enrolled | Japan: 1 |
| Country: Number of subjects enrolled | United States: 2 |
| Worldwide total number of subjects | 20 |
| EEA total number of subjects | 11 |

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 | 0 |

| | |
|---------------------------|----|
| months) | |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 10 |
| From 65 to 84 years | 9 |
| 85 years and over | 1 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

20 participants were randomized and treated.

Period 1

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

Arms

| | |
|------------------------------|------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Nivolumab + BMS-986205 |

Arm description:

Nivolumab 480 mg IV Q4W + BMS-986205 100 mg PO QD

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

480 mg IV Q4W

| | |
|--|------------|
| Investigational medicinal product name | BMS-986205 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

100 mg QD

| | |
|------------------|-----------|
| Arm title | Nivolumab |
|------------------|-----------|

Arm description:

Nivolumab 480 mg IV Q4W

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

480 mg IV Q4W

| Number of subjects in period 1 | Nivolumab + BMS-986205 | Nivolumab |
|--|------------------------|-----------|
| Started | 10 | 10 |
| Completed | 2 | 1 |
| Not completed | 8 | 9 |
| Participant request to discontinue treatment | - | 1 |
| Disease progression | 4 | 6 |
| Participant withdrew consent | 1 | - |
| Study drug toxicity | 1 | - |
| Other reasons | 2 | 2 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|------------------------|
| Reporting group title | Nivolumab + BMS-986205 |
|-----------------------|------------------------|

Reporting group description:

Nivolumab 480 mg IV Q4W + BMS-986205 100 mg PO QD

| | |
|-----------------------|-----------|
| Reporting group title | Nivolumab |
|-----------------------|-----------|

Reporting group description:

Nivolumab 480 mg IV Q4W

| Reporting group values | Nivolumab + BMS-986205 | Nivolumab | Total |
|---|------------------------|-----------|-------|
| Number of subjects | 10 | 10 | 20 |
| Age Categorical | | | |
| Units: Participants | | | |
| <=18 years | 0 | 0 | 0 |
| Between 18 and 65 years | 4 | 6 | 10 |
| >=65 years | 6 | 4 | 10 |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | 4 | 4 | 8 |
| Male | 6 | 6 | 12 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 1 | 1 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 10 | 8 | 18 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 1 | 1 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 1 | 1 |
| Not Hispanic or Latino | 6 | 5 | 11 |
| Unknown or Not Reported | 4 | 4 | 8 |

End points

End points reporting groups

| | |
|---|------------------------|
| Reporting group title | Nivolumab + BMS-986205 |
| Reporting group description: Nivolumab 480 mg IV Q4W + BMS-986205 100 mg PO QD | |
| Reporting group title | Nivolumab |
| Reporting group description: Nivolumab 480 mg IV Q4W | |

Primary: Number of Participants Experiencing Adverse Events

| | |
|--|---|
| End point title | Number of Participants Experiencing Adverse Events ^[1] |
| End point description: Number of participants experiencing different types of Adverse Events, including Death, Any cause Adverse Events (AEs), Drug-related AEs, Any cause Serious Adverse Events (SAEs), Drug-related SAEs, SAEs leading to discontinuation, and Drug-related Non-serious AEs leading to discontinuation | |
| End point type | Primary |
| End point timeframe: From first dose to 100 days following last dose (up to approximately 27 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: No statistical analysis was performed for this endpoint.

| End point values | Nivolumab + BMS-986205 | Nivolumab | | |
|---|------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: Participants | | | | |
| Deaths | 1 | 1 | | |
| Any cause AEs (any grade) | 10 | 9 | | |
| Drug-related AEs (any grade) | 9 | 7 | | |
| Any cause SAEs (any grade) | 3 | 3 | | |
| Drug-related SAEs (any grade) | 1 | 0 | | |
| SAEs leading to discontinuation | 1 | 0 | | |
| Drug-Related Non-serious AEs leading to disc. | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All adverse events were collected from the first dose up to 30 days (inclusive) after the last dose of study treatment

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 23.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------------------|
| Reporting group title | NIVOLUMAB + BMS-986205 |
|-----------------------|------------------------|

Reporting group description:

Subjects were orally administered with BMS-986205 100 milligrams (mg) once daily (QD) after a meal along with Nivolumab 480 mg as a 30-minute intravenous (IV) infusion every 4 weeks for up to 104 weeks.

| | |
|-----------------------|-----------|
| Reporting group title | NIVOLUMAB |
|-----------------------|-----------|

Reporting group description:

Subjects were administered Nivolumab 480 mg as a 30-minute IV infusion every 4 weeks for up to 104 weeks.

| Serious adverse events | NIVOLUMAB + BMS-986205 | NIVOLUMAB | |
|---|------------------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 3 / 10 (30.00%) | |
| number of deaths (all causes) | 1 | 3 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Constipation | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Renal and urinary disorders | | | |
| Renal failure | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | NIVOLUMAB + BMS-986205 | NIVOLUMAB | |
|---|-------------------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 10 / 10 (100.00%) | 9 / 10 (90.00%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 2 | |
| Hypotension | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|--|-----------------|-----------------|--|
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 5 / 10 (50.00%) | 2 / 10 (20.00%) | |
| occurrences (all) | 6 | 2 | |
| Chest discomfort | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Fatigue | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 2 / 10 (20.00%) | |
| occurrences (all) | 2 | 2 | |
| Influenza like illness | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 2 | 1 | |
| Mucosal inflammation | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 1 | 1 | |
| Pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Reproductive system and breast disorders | | | |
| Breast pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pelvic pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Pruritus genital | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 2 | |

| | | | |
|---|-----------------|-----------------|--|
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 10 (20.00%) | |
| occurrences (all) | 1 | 2 | |
| Dyspnoea | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 1 | 1 | |
| Hiccups | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Obstructive airways disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Depressed mood | | | |

| | | | |
|--|----------------------|----------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 10 (10.00%) 1 | |
| Investigations | | | |
| Amylase increased subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 3 | 0 / 10 (0.00%) 0 | |
| Blood bilirubin increased subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 10 (0.00%) 0 | |
| C-reactive protein increased subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 10 (10.00%) 1 | |
| Lipase increased subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 5 | 0 / 10 (0.00%) 0 | |
| Transaminases increased subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 10 (10.00%) 1 | |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 2 / 10 (20.00%) 2 | |
| Procedural pain subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 10 (0.00%) 0 | |
| Radiation injury subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 10 (0.00%) 0 | |
| Nervous system disorders | | | |
| Dysgeusia subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 1 / 10 (10.00%) 1 | |
| Headache subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 2 / 10 (20.00%) 2 | |
| Lethargy | | | |

| | | | |
|-----------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Neuralgia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Presyncope | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tremor | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eye disorders | | | |
| Dry eye | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ocular discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Vitreous floaters | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gastrointestinal disorders | | | |
| Abdominal distension | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abdominal pain upper | | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Constipation | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 2 | 1 | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 10 (20.00%) | |
| occurrences (all) | 1 | 2 | |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 1 | 1 | |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nausea | | | |
| subjects affected / exposed | 5 / 10 (50.00%) | 3 / 10 (30.00%) | |
| occurrences (all) | 5 | 5 | |
| Proctalgia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Stomatitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 10 (20.00%) | |
| occurrences (all) | 1 | 2 | |
| Skin and subcutaneous tissue disorders | | | |
| Dry skin | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Itching scar | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Pruritus | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 10 (20.00%) | |
| occurrences (all) | 0 | 2 | |
| Rash macular | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Sensitive skin | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Skin lesion | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Solar dermatitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Renal and urinary disorders | | | |
| Urinary incontinence | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Thyroiditis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 3 / 10 (30.00%) | |
| occurrences (all) | 2 | 4 | |

| | | | |
|-----------------------------------|-----------------|-----------------|--|
| Bone pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Flank pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 1 | 1 | |
| Myalgia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 10 (20.00%) | |
| occurrences (all) | 0 | 2 | |
| Pain in jaw | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Synovitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Trigger finger | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Infections and infestations | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 10 (20.00%) | |
| occurrences (all) | 0 | 2 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 0 | 1 | |
| Urinary tract infection | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 2 | 1 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 1 / 10 (10.00%) | |
| occurrences (all) | 3 | 2 | |
| Polydipsia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 10 (0.00%) | |
| occurrences (all) | 2 | 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|---|
| 13 June 2018 | Enrollment of new subjects closed; treatment allocation unblinded; efficacy, PK, biomarker and PRO assessments will no longer be evaluated. |
| 25 October 2018 | Study unblinded |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported