



Clinical trial results:

A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy and Safety of BMS-986165 in Subjects With Systemic Lupus Erythematosus

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2017-001203-79 |
| Trial protocol | HU PL DE ES RO |
| Global end of trial date | 28 October 2021 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 15 December 2022 |
| First version publication date | 15 December 2022 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | IM011-021 |
|-----------------------|-----------|

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 | 14 January 2022 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 28 October 2021 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy and safety of BMS-986165 in subjects with Systemic Lupus Erythematosus

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 | 21 September 2017 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Japan: 19 |
| Country: Number of subjects enrolled | Argentina: 19 |
| Country: Number of subjects enrolled | Brazil: 32 |
| Country: Number of subjects enrolled | Colombia: 24 |
| Country: Number of subjects enrolled | Mexico: 33 |
| Country: Number of subjects enrolled | Canada: 2 |
| Country: Number of subjects enrolled | United States: 85 |
| Country: Number of subjects enrolled | Australia: 1 |
| Country: Number of subjects enrolled | Germany: 1 |
| Country: Number of subjects enrolled | Hungary: 11 |
| Country: Number of subjects enrolled | Israel: 1 |
| Country: Number of subjects enrolled | Korea, Republic of: 3 |
| Country: Number of subjects enrolled | Poland: 51 |
| Country: Number of subjects enrolled | Romania: 14 |
| Country: Number of subjects enrolled | Russian Federation: 44 |
| Country: Number of subjects enrolled | Spain: 7 |
| Country: Number of subjects enrolled | Taiwan: 16 |
| Worldwide total number of subjects | 363 |
| EEA total number of subjects | 84 |

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) | 354 |
| From 65 to 84 years | 9 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

363 Participants randomized and treated

Period 1

| | |
|------------------------------|---------------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Carer |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Placebo PO BID

| | |
|--|----------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Placebo Matching BMS-986165

| | |
|------------------|-----------------|
| Arm title | BMS-986165 3 mg |
|------------------|-----------------|

Arm description:

BMS-986165 3 mg PO BID

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-986165 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

3 mg PO BID

| | |
|------------------|-----------------|
| Arm title | BMS-986165 6 mg |
|------------------|-----------------|

Arm description:

BMS-986165 6 mg PO BID

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-986165 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

6 mg PO BID

| | |
|---|----------------------------|
| Arm title | BMS-986165 12 mg |
| Arm description: BMS-986165 12 mg PO QD | |
| Arm type | Experimental |
| Investigational medicinal product name | BMS-986165 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Intratumoral use, Oral use |
| Dosage and administration details: 12 mg PO QD | |

| Number of subjects in period 1 | Placebo | BMS-986165 3 mg | BMS-986165 6 mg |
|---------------------------------------|---------|-----------------|-----------------|
| Started | 90 | 91 | 93 |
| Completed | 66 | 71 | 76 |
| Not completed | 24 | 20 | 17 |
| Consent withdrawn by subject | 8 | 4 | 4 |
| Adverse event, non-fatal | 3 | 8 | 6 |
| Other Reasons | 2 | 5 | 5 |
| Pregnancy | 2 | 1 | - |
| Lost to follow-up | 2 | - | - |
| Lack of efficacy | 7 | 2 | 2 |

| Number of subjects in period 1 | BMS-986165 12 mg |
|---------------------------------------|------------------|
| Started | 89 |
| Completed | 62 |
| Not completed | 27 |
| Consent withdrawn by subject | 4 |
| Adverse event, non-fatal | 12 |
| Other Reasons | 4 |
| Pregnancy | 1 |
| Lost to follow-up | 2 |
| Lack of efficacy | 4 |

Baseline characteristics

Reporting groups

| | |
|------------------------------|------------------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Placebo PO BID | |
| Reporting group title | BMS-986165 3 mg |
| Reporting group description: | |
| BMS-986165 3 mg PO BID | |
| Reporting group title | BMS-986165 6 mg |
| Reporting group description: | |
| BMS-986165 6 mg PO BID | |
| Reporting group title | BMS-986165 12 mg |
| Reporting group description: | |
| BMS-986165 12 mg PO QD | |

| Reporting group values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg |
|------------------------|---------|-----------------|-----------------|
| Number of subjects | 90 | 91 | 93 |
| Age categorical | | | |
| Units: | | | |

| | | | |
|---|--------|--------|--------|
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 40.1 | 40.2 | 40.9 |
| standard deviation | ± 13.1 | ± 11.9 | ± 12.5 |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | 80 | 85 | 88 |
| Male | 10 | 6 | 5 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 4 | 3 | 5 |
| Asian | 10 | 9 | 15 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 6 | 10 | 8 |
| White | 60 | 62 | 55 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 10 | 7 | 10 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 31 | 31 | 29 |
| Not Hispanic or Latino | 58 | 60 | 64 |
| Unknown or Not Reported | 1 | 0 | 0 |

| Reporting group values | BMS-986165 12 mg | Total | |
|------------------------|------------------|-------|--|
| Number of subjects | 89 | 363 | |

| | | | |
|---|----------------|-----|--|
| Age categorical Units: | | | |
| Age Continuous Units: years arithmetic mean standard deviation | 39.0 ± 10.6 | - | |
| Sex: Female, Male Units: Participants | | | |
| Female | 81 | 334 | |
| Male | 8 | 29 | |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 2 | 14 | |
| Asian | 10 | 44 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Black or African American | 9 | 33 | |
| White | 57 | 234 | |
| More than one race | 0 | 0 | |
| Unknown or Not Reported | 11 | 38 | |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 36 | 127 | |
| Not Hispanic or Latino | 53 | 235 | |
| Unknown or Not Reported | 0 | 1 | |

End points

End points reporting groups

| | |
|--|------------------|
| Reporting group title | Placebo |
| Reporting group description: Placebo PO BID | |
| Reporting group title | BMS-986165 3 mg |
| Reporting group description: BMS-986165 3 mg PO BID | |
| Reporting group title | BMS-986165 6 mg |
| Reporting group description: BMS-986165 6 mg PO BID | |
| Reporting group title | BMS-986165 12 mg |
| Reporting group description: BMS-986165 12 mg PO QD | |

Primary: Number of Participants Who Meet Response Criteria for Systemic Lupus Erythematosus (SLE) Responder Index [SRI(4)] at Week 32

| | |
|---|--|
| End point title | Number of Participants Who Meet Response Criteria for Systemic Lupus Erythematosus (SLE) Responder Index [SRI(4)] at Week 32 |
| End point description: SRI(4) responder is defined as a patient whose disease course fulfills all of the following: (1) A 4-point or greater reduction from baseline in SLEDAI-2K score (2) No new British Isles Lupus Assessment Group (BILAG) A (severe disease activity) and not more than 1 new BILAG B (moderate disease activity) organ domain grade (3) No worsening from baseline in the Physician's Global Assessment of Disease Activity Scale by more than 0.3 points on a 3-point visual analog scale from no disease activity to severe disease activity | |
| End point type | Primary |
| End point timeframe: At week 32 | |

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|-----------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Participants | 31 | 53 | 46 | 40 |

Statistical analyses

| | |
|---|---------------------------------------|
| Statistical analysis title | Odds Ratio BMS-986165 3 mg vs Placebo |
| Statistical analysis description: BMS-986165 3 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 3 mg |

| | |
|---|----------------------|
| Number of subjects included in analysis | 181 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0006 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 2.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.5 |
| upper limit | 5.1 |

| | |
|--|--|
| Statistical analysis title | Odds Ratio BMS-986165 12 mg vs Placebo |
| Statistical analysis description: BMS-986165 12 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 12 mg |
| Number of subjects included in analysis | 179 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0781 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8 |
| upper limit | 2.9 |

| | |
|---|---------------------------------------|
| Statistical analysis title | Odds Ratio BMS-986165 6 mg vs Placebo |
| Statistical analysis description: BMS-986165 6 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 6 mg |
| Number of subjects included in analysis | 183 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.021 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1 |
| upper limit | 3.4 |

Secondary: Number of Participants Who Meet Response Criteria for Systemic Lupus Erythematosus (SLE) Responder Index [SRI(4)] at Week 48

| | |
|-----------------|--|
| End point title | Number of Participants Who Meet Response Criteria for Systemic Lupus Erythematosus (SLE) Responder Index [SRI(4)] at Week 48 |
|-----------------|--|

End point description:

SRI(4) responder is defined as a patient whose disease course fulfills all of the following:

- (1) A 4-point or greater reduction from baseline in SLEDAI-2K score
- (2) No new British Isles Lupus Assessment Group (BILAG) A (severe disease activity) or not more than 1 new BILAG B (moderate disease activity) organ domain grade
- (3) No worsening from baseline in the Physician's Global Assessment of Disease Activity Scale by more than 0.3 points on a 3-point visual analog scale from no disease activity to severe disease activity

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At week 48

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|-----------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Participants | 31 | 52 | 44 | 42 |

Statistical analyses

| | |
|----------------------------|---------------------------------------|
| Statistical analysis title | Odds Ratio BMS-986165 3 mg vs Placebo |
|----------------------------|---------------------------------------|

Statistical analysis description:

BMS-986165 3 mg vs Placebo

| | |
|-------------------|---------------------------|
| Comparison groups | Placebo v BMS-986165 3 mg |
|-------------------|---------------------------|

| | |
|---|-----|
| Number of subjects included in analysis | 181 |
|---|-----|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|--|
| Analysis type | |
|---------------|--|

| | |
|---------|----------|
| P-value | = 0.0011 |
|---------|----------|

| | |
|--------|----------------------|
| Method | Regression, Logistic |
|--------|----------------------|

| | |
|--------------------|-----------------|
| Parameter estimate | Odds ratio (OR) |
|--------------------|-----------------|

| | |
|----------------|-----|
| Point estimate | 2.6 |
|----------------|-----|

Confidence interval

| | |
|-------|------|
| level | 95 % |
|-------|------|

| | |
|-------|---------|
| sides | 2-sided |
|-------|---------|

| | |
|-------------|-----|
| lower limit | 1.4 |
|-------------|-----|

| | |
|-------------|-----|
| upper limit | 4.8 |
|-------------|-----|

| | |
|----------------------------|---------------------------------------|
| Statistical analysis title | Odds Ratio BMS-986165 6 mg vs Placebo |
|----------------------------|---------------------------------------|

Statistical analysis description:

BMS-986165 6 mg vs Placebo

| | |
|---|---------------------------|
| Comparison groups | Placebo v BMS-986165 6 mg |
| Number of subjects included in analysis | 183 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0434 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 3.1 |

Statistical analysis title

Odds Ratio BMS-986165 12 mg vs Placebo

Statistical analysis description:

BMS-986165 12 mg vs Placebo

| | |
|---|----------------------------|
| Comparison groups | Placebo v BMS-986165 12 mg |
| Number of subjects included in analysis | 179 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0439 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 3.1 |

Secondary: Number of Participants Who Achieve British Isles Lupus Assessment Group-Based Composite Lupus Assessment (BICLA) Response

| | |
|-----------------|---|
| End point title | Number of Participants Who Achieve British Isles Lupus Assessment Group-Based Composite Lupus Assessment (BICLA) Response |
|-----------------|---|

End point description:

BICLA responder is defined as a patient whose disease course fulfills all of the following:

- (1) Improvement in all organ systems with activity graded as BILAG-2004 A (severe disease activity) or B (moderate disease activity) at baseline
- (2) No new organ system with activity graded as BILAG A; no more than 1 new organ system with activity graded as BILAG B
- (3) No increase from baseline in Systemic Lupus Erythematosus SLEDAI-2K score (≤ 0 points for change from baseline score)
- (4) No increase $\geq 10\%$ in the Physician's Global Assessment of Disease Activity on a 3-point visual analog scale from no disease activity to severe disease activity
- (5) No discontinuation of investigational product or use of restricted medications beyond the protocol allowed threshold before assessment

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At week 48 | |

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|-----------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Participants | 23 | 43 | 33 | 32 |

Statistical analyses

| Statistical analysis title | Odds Ratio BMS-986165 3 mg vs Placebo |
|---|---------------------------------------|
| Statistical analysis description: BMS-986165 3 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 3 mg |
| Number of subjects included in analysis | 181 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0012 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 2.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.4 |
| upper limit | 5.1 |

| Statistical analysis title | Odds Ratio BMS-986165 12 mg vs Placebo |
|--|--|
| Statistical analysis description: BMS-986165 12 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 12 mg |
| Number of subjects included in analysis | 179 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0673 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.6 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 3.2 |

| | |
|---|---------------------------------------|
| Statistical analysis title | Odds Ratio BMS-986165 6 mg vs Placebo |
| Statistical analysis description: BMS-986165 6 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 6 mg |
| Number of subjects included in analysis | 183 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0795 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8 |
| upper limit | 3 |

Secondary: Number of Participants Who Achieve Lupus Low Disease Activity State (LLDAS)

| | |
|--|---|
| End point title | Number of Participants Who Achieve Lupus Low Disease Activity State (LLDAS) |
| End point description: LLDAS is defined as follows: (1) SLEDAI-2K \leq 4, with no activity in major organ systems (renal, central nervous system, cardiopulmonary, vasculitis, fever) and no hemolytic anemia or gastrointestinal activity measured as maintaining a D (no disease activity but suggests the system had previously been affected) or E (no current or previous disease activity) score in BILAG Gastrointestinal Body System (2) No new lupus disease activity compared with the previous assessment measured as no new or worsening individual BILAG parameters (3) Physician's Global Assessment of Disease Activity \leq 1 on a 3-point visual analog scale from no disease activity to severe disease activity (4) A current prednisolone (or equivalent) dose \leq 7.5 mg daily (5) Well-tolerated standard maintenance doses of immunosuppressive drugs and approved biological agents | |
| End point type | Secondary |
| End point timeframe: At Week 48 | |

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|-----------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Participants | 12 | 33 | 22 | 23 |

Statistical analyses

| Statistical analysis title | Odds Ratio BMS-986165 3 mg vs Placebo |
|---|---------------------------------------|
| Statistical analysis description: BMS-986165 3 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 3 mg |
| Number of subjects included in analysis | 181 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0002 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.9 |
| upper limit | 8.5 |

| Statistical analysis title | Odds Ratio BMS-986165 12 mg vs Placebo |
|--|--|
| Statistical analysis description: BMS-986165 12 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 12 mg |
| Number of subjects included in analysis | 179 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0168 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 2.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.1 |
| upper limit | 5.1 |

| Statistical analysis title | Odds Ratio BMS-986165 6 mg vs Placebo |
|-----------------------------------|---------------------------------------|
|-----------------------------------|---------------------------------------|

| | |
|---|---------------------------|
| Statistical analysis description: BMS-986165 6 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 6 mg |
| Number of subjects included in analysis | 183 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0371 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 4.5 |

Secondary: Number of Participants With a $\geq 50\%$ Reduction in CLASI Activity Score in the Sub-group With Baseline CLASI Activity Score ≥ 10

| | |
|--|---|
| End point title | Number of Participants With a $\geq 50\%$ Reduction in CLASI Activity Score in the Sub-group With Baseline CLASI Activity Score ≥ 10 |
| End point description: Number of participants with a Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) activity score ≥ 10 at baseline who achieve a CLASI response, defined as a decrease of $\geq 50\%$ from baseline CLASI activity score (ranges from 0-70, where a higher score is associated with high disease activity). CLASI assesses by body surface area; points are given for presence of erythema, scale, hypertrophy, mucous membrane lesions, recent hair loss, and physician-observed alopecia | |
| End point type | Secondary |
| End point timeframe: At week 48 | |

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|-----------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 24 | 23 | 25 | 29 |
| Units: Participants | 4 | 16 | 14 | 18 |

Statistical analyses

| | |
|---|---------------------------------------|
| Statistical analysis title | Odds Ratio BMS-986165 3 mg vs Placebo |
| Statistical analysis description: BMS-986165 3 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 3 mg |

| | |
|---|----------------------|
| Number of subjects included in analysis | 47 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0006 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 10.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.5 |
| upper limit | 43 |

| | |
|--|--|
| Statistical analysis title | Odds Ratio BMS-986165 12 mg vs Placebo |
| Statistical analysis description: BMS-986165 12 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 12 mg |
| Number of subjects included in analysis | 53 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0009 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 8.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.2 |
| upper limit | 31 |

| | |
|---|---------------------------------------|
| Statistical analysis title | Odds Ratio BMS-986165 6 mg vs Placebo |
| Statistical analysis description: BMS-986165 6 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 6 mg |
| Number of subjects included in analysis | 49 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0058 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 5.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.5 |
| upper limit | 22 |

Secondary: Change from Baseline in the 40-Joint Count

| | |
|--|--|
| End point title | Change from Baseline in the 40-Joint Count |
| End point description: | |
| Change from baseline in the following 40-joint count: phalangeal joints of the hand, second through fifth metacarpophalangeal joints of the hand, and individual metatarsophalangeal joints of the feet, Bilateral first metacarpophalangeal joints and shoulders. Each of 40 joints count is evaluated based upon the presence or absence of: (1) Tender joint count (0 to 40) (2) Swollen joint count (0 to 40) (3) Tender and swollen joint count (0 to 40) A larger joint count indicates more severe disease. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline and week 48 | |

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|--------------------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Units on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Tender | -11.2 (± 8.0) | -12.2 (± 7.5) | -11.7 (± 9.5) | -12.3 (± 7.1) |
| Swollen | -8.3 (± 6.9) | -8.5 (± 4.2) | -8.8 (± 7.2) | -9.9 (± 6.1) |
| Tender + Swollen | -8.2 (± 6.7) | -8.2 (± 4.3) | -8.5 (± 7.0) | -9.7 (± 5.9) |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Odd Ratio Tender BMS-986165 3 mg vs Placebo |
| Statistical analysis description: | |
| Tender BMS-986165 3 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 3 mg |
| Number of subjects included in analysis | 181 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0131 |
| Method | Longitudinal Repeated Measures |
| Parameter estimate | Adjusted Mean Difference |
| Point estimate | -2.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.4 |
| upper limit | -0.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.04 |

| | |
|--|---|
| Statistical analysis title | Odd Ratio Tender BMS-986165 6 mg vs Placebo |
| Statistical analysis description: Tender BMS-986165 6 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 6 mg |
| Number of subjects included in analysis | 183 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.4156 |
| Method | Longitudinal Repeated Measures |
| Parameter estimate | Adjusted Mean Difference |
| Point estimate | -0.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.3 |
| upper limit | 1.8 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.04 |

| | |
|---|--|
| Statistical analysis title | Odd Ratio Tender BMS-986165 12 mg vs Placebo |
| Statistical analysis description: Tender BMS-986165 12 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 12 mg |
| Number of subjects included in analysis | 179 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0151 |
| Method | Longitudinal Repeated Measures |
| Parameter estimate | Adjusted Mean Difference |
| Point estimate | -2.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.5 |
| upper limit | -0.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.09 |

| | |
|---|--|
| Statistical analysis title | Odd Ratio Swollen BMS-986165 3 mg vs Placebo |
| Statistical analysis description: Swollen BMS-986165 3 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 3 mg |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 181 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0029 |
| Method | Longitudinal Repeated Measures |
| Parameter estimate | Adjusted Mean Difference |
| Point estimate | -1.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.2 |
| upper limit | -0.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.45 |

| | |
|---|--|
| Statistical analysis title | Odd Ratio Swollen BMS-986165 6 mg vs Placebo |
| Statistical analysis description: | |
| Swollen BMS-986165 6 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 6 mg |
| Number of subjects included in analysis | 183 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0516 |
| Method | Longitudinal Repeated Measures |
| Parameter estimate | Adjusted Mean Difference |
| Point estimate | -0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.6 |
| upper limit | 0.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.46 |

| | |
|---|--|
| Statistical analysis title | OR Tender + Swollen BMS-986165 3 mg vs Placebo |
| Statistical analysis description: | |
| Tender + Swollen BMS-986165 3 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 3 mg |
| Number of subjects included in analysis | 181 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.001 |
| Method | Longitudinal Repeated Measures |
| Parameter estimate | Adjusted Mean Difference |
| Point estimate | -1.2 |

| | |
|----------------------|----------------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2 |
| upper limit | -0.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.4 |

| | |
|--|---|
| Statistical analysis title | Odd Ratio Swollen BMS-986165 12 mg vs Placebo |
| Statistical analysis description: Swollen BMS-986165 12 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 12 mg |
| Number of subjects included in analysis | 179 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0298 |
| Method | Longitudinal Repeated Measures |
| Parameter estimate | Adjusted Mean Difference |
| Point estimate | -0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.8 |
| upper limit | 0 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.48 |

| | |
|--|--|
| Statistical analysis title | OR Tender + Swollen BMS-986165 6 mg vs Placebo |
| Statistical analysis description: Tender + Swollen BMS-986165 6 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 6 mg |
| Number of subjects included in analysis | 183 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0343 |
| Method | Longitudinal Repeated Measures |
| Parameter estimate | Adjusted Mean Difference |
| Point estimate | -0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.5 |
| upper limit | 0.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.4 |

| | |
|---|---|
| Statistical analysis title | OR Tender + Swollen BMS-986165 12 mg vs Placebo |
| Statistical analysis description: Tender + Swollen BMS-986165 12 mg vs Placebo | |
| Comparison groups | Placebo v BMS-986165 12 mg |
| Number of subjects included in analysis | 179 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.005 |
| Method | Longitudinal Repeated Measures |
| Parameter estimate | Adjusted Mean Difference |
| Point estimate | -1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.9 |
| upper limit | -0.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.42 |

Secondary: Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs)

| | |
|-----------------|--|
| End point title | Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs) |
|-----------------|--|

End point description:

Number of participants with any grade adverse events (AEs) and any grade serious adverse events (SAEs). An adverse event (AE) including SAEs is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in participants that do not necessarily have causal relationship with treatment

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose to 30 days post last dose (Up to 52 weeks)

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|-----------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Participants | | | | |
| AEs | 79 | 85 | 81 | 75 |
| SAEs | 11 | 7 | 8 | 7 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Laboratory Abnormalities in Specific Liver Tests

| | |
|-----------------|--|
| End point title | Number of Participants with Laboratory Abnormalities in Specific Liver Tests |
|-----------------|--|

End point description:

Number of participants with laboratory abnormalities in specific liver tests based on US conventional units. The potential drug-induced liver injury is defined by the presence of all of the following:

- (1) Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST) elevation > 3× Upper Limit of Normal (ULN)
- (2) Total bilirubin > 2× ULN, without initial findings of cholestasis (elevated serum alkaline phosphatase)
- (3) No other immediately apparent possible causes of AST or ALT elevation and hyperbilirubinemia, including, but not limited to, viral hepatitis, preexisting chronic or acute liver disease, or the administration of other drug(s) known to be hepatotoxic

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose to 30 days post last dose (Up to 52 weeks)

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|--|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Participants | | | | |
| ALT or AST > 3XULN | 2 | 5 | 3 | 2 |
| ALT or AST > 5XULN | 2 | 1 | 1 | 1 |
| Total Bilirubin > 2XULN | 0 | 0 | 0 | 0 |
| ALT or AST>3XULN and Total Bilirubin>2XULN | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormalities in Vital Signs

| | |
|-----------------|--|
| End point title | Number of Participants with Abnormalities in Vital Signs |
|-----------------|--|

End point description:

Number of participants with abnormalities in vital signs including heart rate, systolic blood pressure, and diastolic blood pressure

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From first dose to 30 days post last dose (Up to 52 weeks)

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|--|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 88 | 91 | 87 |
| Units: Participants | | | | |
| Wk 2: HR: Value>100 and change from baseline>30 | 0 | 0 | 0 | 0 |
| Wk 2: HR: Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 2 SBP: Value>140 and change from baseline>20 | 1 | 1 | 0 | 1 |
| Wk 2 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 2 DBP: Value>90 and change from baseline>10 | 0 | 0 | 1 | 1 |
| Wk 2 DBP: Value<55 and change from baseline<-10 | 0 | 2 | 1 | 0 |
| Wk 4 HR: Value>100 and change from baseline>30 | 0 | 0 | 1 | 0 |
| Wk 4 HR: Value<55 and change from baseline<-15 | 0 | 1 | 0 | 0 |
| Wk 4 SBP: Value>140 and change from baseline>20 | 0 | 0 | 0 | 1 |
| Wk 4 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 4 DBP: Value>90 and change from baseline>10 | 2 | 0 | 0 | 1 |
| Wk 4 DBP: Value<55 and change from baseline<-10 | 0 | 0 | 0 | 0 |
| Wk 8 HR: Value>100 and change from baseline>30 | 1 | 2 | 0 | 0 |
| Wk 8 HR: Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 8 SBP: Value>140 and change from baseline>20 | 1 | 1 | 1 | 0 |
| Wk 8 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 8 DBP: Value>90 and change from baseline>10 | 0 | 1 | 3 | 1 |
| Wk 8 DBP: Value<55 and change from baseline<-10 | 0 | 1 | 0 | 0 |
| Wk 12 HR: Value>100 and change from baseline>30 | 0 | 0 | 0 | 0 |
| Wk 12 HR: Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 12 SBP: Value>140 and change from baseline>20 | 1 | 1 | 0 | 0 |
| Wk 12 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 12 DBP: Value>90 and change from baseline>10 | 0 | 3 | 2 | 1 |
| Wk 12 DBP: Value<55 and change from baseline<-10 | 1 | 1 | 1 | 0 |
| Wk 16 HR: Value>100 and change from baseline>30 | 0 | 0 | 0 | 0 |
| Wk 16 HR: Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 16 SBP: Value>140 and change from baseline>20 | 0 | 0 | 0 | 1 |
| Wk 16 SBP: Value<90 and change from baseline<-20 | 1 | 0 | 0 | 0 |

| | | | | |
|--|---|---|---|---|
| Wk 16 DBP: Value>90 and change from baseline>10 | 0 | 1 | 0 | 2 |
| Wk 16 DBP: Value<55 and change from baseline<-10 | 0 | 0 | 0 | 0 |
| Wk 20: HR: Value>100 and change from baseline>30 | 0 | 0 | 0 | 0 |
| Wk 20 HR: Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 20 SBP: Value>140 and change from baseline>20 | 1 | 1 | 0 | 1 |
| Wk 20 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 20 DBP: Value>90 and change from baseline>10 | 2 | 2 | 0 | 2 |
| Wk 20 DBP: Value<55 and change from baseline<-10 | 0 | 0 | 0 | 0 |
| Wk 24 HR: Value>100 and change from baseline>30 | 1 | 0 | 0 | 0 |
| Wk 24 HR: Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 24 SBP: Value>140 and change from baseline>20 | 0 | 1 | 0 | 1 |
| Wk 24 SBP: Value<90 and change from baseline<-20 | 0 | 1 | 0 | 0 |
| Wk 24 DBP: Value>90 and change from baseline>10 | 0 | 1 | 0 | 2 |
| Wk 24 DBP: Value<55 and change from baseline<-10 | 0 | 1 | 0 | 0 |
| Wk 28 HR Value>100 and change from baseline>30 | 0 | 0 | 0 | 0 |
| Wk 28 HR: Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 28 SBP: Value>140 and change from baseline>20 | 1 | 3 | 1 | 3 |
| Wk 28 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 1 | 0 |
| Wk 28 DBP: Value>90 and change from baseline>10 | 1 | 4 | 0 | 2 |
| Wk 28 DBP: Value<55 and change from baseline<-10 | 0 | 1 | 0 | 0 |
| Wk 32 HR: Value>100 and change from baseline>30 | 0 | 2 | 1 | 0 |
| Wk 32 HR Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 32 SBP: Value>140 and change from baseline>20 | 1 | 1 | 0 | 3 |
| Wk 32 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 32 DBP: Value>90 and change from baseline>10 | 1 | 1 | 2 | 3 |
| Wk 32 DBP: Value<55 and change from baseline<-10 | 0 | 1 | 0 | 0 |
| Wk 36 HR: Value>100 and change from baseline>30 | 0 | 1 | 0 | 0 |
| Wk 36 HR: Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 36 SBP: Value>140 and change from baseline>20 | 0 | 0 | 0 | 1 |
| Wk 36 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 36 DBP: Value>90 and change from baseline>10 | 1 | 1 | 1 | 2 |

| | | | | |
|---|---|---|---|---|
| Wk 36 DBP: Value<55 and change from baseline<-10 | 0 | 0 | 0 | 0 |
| Wk 40 HR: Value>100 and change from baseline>30 | 0 | 0 | 0 | 0 |
| Wk 40 HR: Value<55 and change from baseline<-15 | 1 | 0 | 0 | 0 |
| Wk 40 SBP: Value>140 and change from baseline>20 | 1 | 0 | 0 | 2 |
| Wk 40 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 40 DBP: Value>90 and change from baseline>10 | 0 | 2 | 1 | 1 |
| Wk 40 DBP: Value<55 and change from baseline<-10 | 0 | 0 | 0 | 0 |
| Wk 44 HR: Value>100 and change from baseline>30 | 0 | 0 | 0 | 0 |
| Wk 44 HR: Value<55 and change from baseline<-15 | 0 | 0 | 1 | 0 |
| Wk 44 SBP: Value>140 and change from baseline>20 | 0 | 0 | 0 | 0 |
| Wk 44 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 44 DBP: Value>90 and change from baseline>10 | 0 | 0 | 1 | 2 |
| Wk 44 DBP: Value<55 and change from baseline<-10 | 1 | 1 | 0 | 0 |
| Wk 48 HR: Value>100 and change from baseline>30 | 0 | 0 | 0 | 0 |
| Wk 48 HR: Value<55 and change from baseline<-15 | 0 | 0 | 0 | 0 |
| Wk 48 SBP: Value>140 and change from baseline>20 | 2 | 0 | 0 | 0 |
| Wk 48: SBP: Value<90 and change from baseline<-20 | 0 | 1 | 0 | 0 |
| Wk 48 DBP: Value>90 and change from baseline>10 | 2 | 1 | 0 | 0 |
| Wk 48 DBP: Value<55 and change from baseline<-10 | 0 | 0 | 0 | 0 |
| Wk 52 HR: Value>100 and change from baseline>30 | 0 | 0 | 0 | 0 |
| Wk 52 HR: Value<55 and change from baseline<-15 | 0 | 1 | 0 | 0 |
| Wk 52 SBP: Value>140 and change from baseline>20 | 0 | 0 | 0 | 0 |
| Wk 52 SBP: Value<90 and change from baseline<-20 | 0 | 0 | 0 | 0 |
| Wk 52 DBP: Value>90 and change from baseline>10 | 0 | 0 | 0 | 1 |
| Wk 52 DBP: Value<55 and change from baseline<-10 | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormalities in Electrocardiograms (ECGs)

| | |
|-----------------|--|
| End point title | Number of Participants with Abnormalities in Electrocardiograms (ECGs) |
|-----------------|--|

End point description:

Number of participants with abnormalities in electrocardiograms (ECGs) assessed by QTcF, PR interval, and QRS interval

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From baseline to up to week 48

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|-------------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 89 | 90 | 92 | 89 |
| Units: Participants | | | | |
| Baseline: QTcF 450 to < 480 | 9 | 3 | 6 | 5 |
| Baseline: QTcF 480 to < 500 | 1 | 1 | 0 | 0 |
| Baseline: QTcF >= 500 | 0 | 0 | 1 | 0 |
| Baseline: PR Interval >= 200 | 5 | 4 | 6 | 6 |
| Baseline: QRS Interval >=200 | 0 | 0 | 0 | 0 |
| Week 4: QTcF 450 to < 480 | 5 | 6 | 5 | 6 |
| Week 4: QTcF 480 to < 500 | 0 | 2 | 1 | 0 |
| Week4: QTcF >= 500 | 0 | 0 | 0 | 1 |
| Week 4: PR Interval >= 200 | 7 | 7 | 4 | 5 |
| Week 4: QRS Interval: >= 200 | 0 | 0 | 0 | 0 |
| Week 8: QTcF 450 to < 480 | 7 | 5 | 6 | 1 |
| Week 8: QTcF 480 to < 500 | 0 | 0 | 1 | 2 |
| Week 8: QTcF >=500 | 0 | 0 | 0 | 0 |
| Week 8: PR Interval >= 200 | 5 | 6 | 5 | 6 |
| Week 8 QRS Interval >=200 | 0 | 0 | 0 | 0 |
| Week 12: QTcF 450 to < 480 | 3 | 4 | 6 | 8 |
| Week 12: QTcF 480 to < 500 | 0 | 0 | 0 | 0 |
| Week 12: QTcF >= 500 | 0 | 0 | 0 | 1 |
| Week 12: PR Interval >= 200 | 6 | 8 | 4 | 4 |
| Week 12: QRS Interval >=200 | 0 | 0 | 0 | 0 |
| Week 32: QTcF 450 to < 480 | 5 | 5 | 2 | 5 |
| Week 32: QTcF 480 to < 500 | 0 | 0 | 2 | 0 |
| Week 32: QTcF >=500 | 0 | 0 | 0 | 0 |
| Week 32: PR Interval >= 200 | 5 | 7 | 5 | 5 |
| Week 32: QRS Interval >= 200 | 0 | 0 | 0 | 0 |
| Week 48: QTcF: 450 to < 480 | 7 | 2 | 8 | 5 |
| Week 48: QTcF 480 to < 500 | 0 | 0 | 0 | 0 |
| Week 48: QTcF >=500 | 0 | 0 | 0 | 0 |
| Week 48: PR Interval: >= 200 | 4 | 7 | 6 | 3 |
| Week 48: QRS Interval: >= 200 | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986165 and its Active Metabolite BMT-153261 Maximum Observed Plasma Concentration (Cmax)

| | |
|-----------------|---|
| End point title | BMS-986165 and its Active Metabolite BMT-153261 Maximum Observed Plasma Concentration (Cmax) ^[1] |
|-----------------|---|

End point description:

Maximum observed plasma concentration (Cmax) for the following treatments: BMS-986165 and its active metabolite BMT-153261. Geometric coefficient of variation was not calculated and the arithmetic coefficient of variation (% CV) is being reported.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-dose, 0.5, 2, 4, and 6 hours post dose on week 12

Notes:

[1] - 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: Only pre-specified arms planned for this endpoint

| End point values | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg | |
|---|------------------|------------------|------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 73 | 73 | 47 | |
| Units: NG/ML | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| BMS-986165 | 38.033 (± 57.72) | 76.400 (± 37.72) | 96.249 (± 46.80) | |
| Metabolite BMT-153261 | 6.358 (± 67.77) | 12.133 (± 37.72) | 11.748 (± 67.17) | |

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986165 and its Active Metabolite BMT-153261 Time of Maximum Observed Plasma Concentration (Tmax)

| | |
|-----------------|---|
| End point title | BMS-986165 and its Active Metabolite BMT-153261 Time of Maximum Observed Plasma Concentration (Tmax) ^[2] |
|-----------------|---|

End point description:

Time of maximum observed plasma concentration (Tmax) for the following treatments: BMS-986165 and its active metabolite BMT-153261.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-dose, 0.5, 2, 4, 6, and 10 hours post dose on week 12

Notes:

[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: Only pre-specified arms planned for this endpoint

| End point values | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg | |
|-------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 73 | 73 | 47 | |
| Units: Hours | | | | |
| median (full range (min-max)) | | | | |
| BMS-986165 | 2.0000 (0.467 to 6.000) | 2.0000 (0.500 to 7.533) | 2.0000 (0.500 to 5.100) | |
| Metabolite BMT-153261 | 4.0000 (0.550 to 7.500) | 4.0000 (1.017 to 9.533) | 3.7330 (0.500 to 6.067) | |

Statistical analyses

No statistical analyses for this end point

Secondary: BMS-986165 and its Active Metabolite BMT-153261 Trough Observed Plasma Concentration (C_{trough})

| | |
|-----------------|--|
| End point title | BMS-986165 and its Active Metabolite BMT-153261 Trough Observed Plasma Concentration (C _{trough}) ^[3] |
|-----------------|--|

End point description:

Trough observed plasma concentration (C_{trough}) for the following treatments: BMS-986165 and its active metabolite BMT-153261. Geometric coefficient of variation was not calculated and the arithmetic coefficient of variation (% CV) is being reported.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Pre-dose, 0.5, 2, 4, and 6 hours post dose on week 2, 4, 8, 12, 24, 32, and 48

Notes:

[3] - 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: Only pre-specified arms planned for this endpoint

| End point values | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg | |
|---|--------------------|--------------------|---------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 46 | 52 | 64 | |
| Units: NG/ML | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| BMS-986165 week 2 | 14.3737 (± 60.790) | 29.2909 (± 47.588) | 30.8135 (± 70.340) | |
| BMS-986165 week 4 | 14.6095 (± 53.234) | 22.9170 (± 51.043) | 20.1182 (± 81.084) | |
| BMS-986165 week 8 | 13.0328 (± 69.792) | 12.9587 (± 64.799) | 26.7961 (± 67.090) | |
| BMS-986165 week 12 | 10.7517 (± 93.540) | 28.7751 (± 47.282) | 22.1237 (± 85.920) | |
| BMS-986165 week 24 | 10.2546 (± 66.763) | 13.9273 (± 67.922) | 21.8720 (± 78.559) | |
| BMS-986165 week 32 | 8.5293 (± 60.425) | 15.5285 (± 61.704) | 24.5060 (± 75.647) | |
| BMS-986165 week 48 | 6.8493 (± 70.206) | 21.7890 (± 53.718) | 15.9576 (± 102.367) | |
| Metabolite BMT-153261 week 2 | 4.2667 (± 48.679) | 8.4841 (± 54.717) | 8.7920 (± 61.993) | |

| | | | | |
|-------------------------------|------------------------|------------------------|------------------------|--|
| Metabolite BMT-153261 week 4 | 5.0886 (\pm 56.764) | 7.7803 (\pm 53.563) | 7.2703 (\pm 70.461) | |
| Metabolite BMT-153261 week 8 | 4.1293 (\pm 62.816) | 5.2290 (\pm 71.924) | 8.1451 (\pm 57.216) | |
| Metabolite BMT-153261 week 12 | 3.7325 (\pm 96.323) | 9.3281 (\pm 54.823) | 7.4071 (\pm 82.009) | |
| Metabolite BMT-153261 week 24 | 3.3669 (\pm 56.381) | 5.2229 (\pm 71.104) | 6.6608 (\pm 63.748) | |
| Metabolite BMT-153261 week 32 | 2.9759 (\pm 55.379) | 5.2925 (\pm 63.200) | 6.8734 (\pm 77.329) | |
| Metabolite BMT-153261 week 48 | 2.8708 (\pm 73.450) | 6.8838 (\pm 58.302) | 5.8602 (\pm 75.536) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Interferon-Regulated Gene (IRG) Expression Levels

| | |
|--|---|
| End point title | Percent Change from Baseline in Interferon-Regulated Gene (IRG) Expression Levels |
| End point description: | |
| Percent change from baseline in interferon-regulated gene (IRG) expression levels. IRG-high vs. IRG-low was determined using a 5-interferon (IFN) gene set during the sample collected at screening period. Baseline values are defined as the last measurement before the first dose. | |
| End point type | Secondary |
| End point timeframe: | |
| From baseline to week 44 | |

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|--|-------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Percent Change from Baseline arithmetic mean (standard deviation) | | | | |
| IFN High | -0.8130 (\pm 6.5323) | -39.7478 (\pm 13.0087) | -55.5691 (\pm 21.5313) | -47.5561 (\pm 12.2125) |
| IFN Low | 4.7381 (\pm 8.8696) | -18.0641 (\pm 27.0491) | -36.4510 (\pm 22.4759) | -41.7645 (\pm 26.1519) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Interferon-Regulated Gene (IRG) Expression Levels at Week 32

| | |
|-----------------|--|
| End point title | Percent Change from Baseline in Interferon-Regulated Gene (IRG) Expression Levels at Week 32 |
|-----------------|--|

End point description:

Percent change from baseline in interferon-regulated gene (IRG) expression levels. IRG-high vs. IRG-low was determined using a 5-interferon (IFN) gene set during the sample collected at screening period. Baseline values are defined as the last measurement before the first dose.

| | |
|--------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From baseline to week 32 | |

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|--------------------------------------|--------------------|----------------------|----------------------|----------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Percent Change from Baseline | | | | |
| arithmetic mean (standard deviation) | | | | |
| IFN High | -4.3993 (± 5.2234) | -40.7944 (± 13.5929) | -54.6988 (± 16.7734) | -61.0515 (± 13.8367) |
| IFN Low | -2.6555 (± 9.2649) | -27.4897 (± 20.0078) | -42.8107 (± 19.7669) | -42.9701 (± 23.8323) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Complement Proteins C3 and C4 Levels

| | |
|-----------------|--|
| End point title | Percent Change from Baseline in Complement Proteins C3 and C4 Levels |
|-----------------|--|

End point description:

Percent change from baseline in complement proteins C3 and C4 levels. Baseline values are defined as the last measurement before the first dose.

| | |
|--------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From baseline to week 52 | |

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|----------------------------------|------------------|-----------------|------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 10 | 12 | 14 |
| Units: mg/L | | | | |
| arithmetic mean (standard error) | | | | |
| C3 | 3.57 (± 12.225) | 5.33 (± 6.216) | 7.60 (± 5.315) | 14.74 (± 9.619) |
| C4 | 84.52 (± 88.618) | 3.57 (± 7.146) | 24.96 (± 20.508) | 20.43 (± 12.767) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Complement (C3, C4) Levels at Week 32

| | |
|-----------------|---|
| End point title | Percent Change from Baseline in Complement (C3, C4) Levels at Week 32 |
|-----------------|---|

End point description:

Percent change from baseline in complement proteins C3 and C4 levels. Baseline values are defined as the last measurement before the first dose.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From baseline to week 32

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|----------------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 66 | 75 | 78 | 63 |
| Units: mg/L | | | | |
| arithmetic mean (standard error) | | | | |
| C3 | -0.58 (± 3.038) | 5.78 (± 3.161) | 12.42 (± 2.748) | 10.84 (± 2.896) |
| C4 | -3.27 (± 3.297) | 12.32 (± 4.455) | 16.71 (± 5.012) | 25.13 (± 6.988) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Anti-Double-Stranded DNA (dsDNA) Antibodies Levels

| | |
|-----------------|--|
| End point title | Percent Change from Baseline in Anti-Double-Stranded DNA (dsDNA) Antibodies Levels |
|-----------------|--|

End point description:

Percent change from baseline in anti-double-stranded DNA (dsDNA) levels. Baseline values are defined as the last measurement before the first dose.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From baseline to week 52

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|----------------------------------|-------------------------|-----------------------|------------------------|-----------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 10 | 12 | 14 |
| Units: U/mL | | | | |
| arithmetic mean (standard error) | 276.26 (\pm 316.713) | 16.51 (\pm 28.265) | -31.79 (\pm 10.209) | -19.32 (\pm 8.722) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Anti-Double-Stranded DNA (dsDNA) Levels Antibodies at Week 32

| | |
|---|---|
| End point title | Percent Change from Baseline in Anti-Double-Stranded DNA (dsDNA) Levels Antibodies at Week 32 |
| End point description: Percent change from baseline in anti-double-stranded DNA (dsDNA) levels. Baseline values are defined as the last measurement before the first dose. | |
| End point type | Secondary |
| End point timeframe: From baseline to week 32 | |

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 64 | 75 | 77 | 63 |
| Units: U/mL | | | | |
| arithmetic mean (standard error) | 21.36 (\pm 15.135) | -15.24 (\pm 4.910) | -11.31 (\pm 6.323) | -24.17 (\pm 4.781) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Global Systemic Lupus Erythematosus (SLE) Clinical Response Based on Interferon-Regulated Gene (IRG) Status

| | |
|-----------------|---|
| End point title | Number of Participants With Global Systemic Lupus Erythematosus (SLE) Clinical Response Based on Interferon-Regulated Gene (IRG) Status |
|-----------------|---|

End point description:

Global systemic lupus erythematosus (SLE) clinical response in participants based on interferon-regulated gene (IRG) status (high versus low IRG signature). IRG-high vs. IRG-low was determined using a 5-interferon (IFN) gene set during the sample collected at screening period. SRI(4) responder is defined as a patient whose disease course fulfills all of the following:

- (1) A 4-point or greater reduction from baseline in SLEDAI-2K score
- (2) No new British Isles Lupus Assessment Group (BILAG) A (severe disease activity) or not more than 1 new BILAG B (moderate disease activity) organ domain grade
- (3) No worsening from baseline in the Physician's Global Assessment of Disease Activity Scale by more

than 0.3 points on a 3-point visual analog scale from no disease activity to severe disease activity

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At week 32

| End point values | Placebo | BMS-986165 3 mg | BMS-986165 6 mg | BMS-986165 12 mg |
|-----------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 90 | 91 | 93 | 89 |
| Units: Participants | | | | |
| IFN Low | 10 | 7 | 11 | 5 |
| IFN High | 21 | 46 | 35 | 35 |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious Adverse Events (NSAEs) and Serious Adverse Events (SAEs) are collected from first dose to 30 days post last dose (Up to 52 weeks). Subjects were assessed for Deaths (all causes) from date of randomization to study completion (Up to 49 months)

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 24.1 |

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Placebo PO BID

| | |
|-----------------------|---------------------|
| Reporting group title | BMS-986165 3 mg BID |
|-----------------------|---------------------|

Reporting group description:

BMS-986165 3 mg PO BID

| | |
|-----------------------|---------------------|
| Reporting group title | BMS-986165 6 mg BID |
|-----------------------|---------------------|

Reporting group description:

BMS-986165 6 mg PO BID

| | |
|-----------------------|---------------------|
| Reporting group title | BMS-986165 12 mg QD |
|-----------------------|---------------------|

Reporting group description:

BMS-986165 12 mg PO QD

| Serious adverse events | Placebo | BMS-986165 3 mg BID | BMS-986165 6 mg BID |
|---|------------------|---------------------|---------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 11 / 90 (12.22%) | 7 / 91 (7.69%) | 8 / 93 (8.60%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 1 / 91 (1.10%) | 0 / 93 (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 |
| Squamous cell carcinoma of the vagina | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |

| | | | |
|--|----------------|----------------|----------------|
| Hypertensive crisis | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 1 / 91 (1.10%) | 0 / 93 (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 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous incomplete | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (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 |
| General disorders and administration site conditions | | | |
| Generalised oedema | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (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 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 1 / 91 (1.10%) | 0 / 93 (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 |
| Reproductive system and breast disorders | | | |
| Endometrial hyperplasia | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine haemorrhage | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 1 / 91 (1.10%) | 0 / 93 (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 |
| Interstitial lung disease | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 1 / 93 (1.08%) |
| 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 | | | |
| Forearm fracture | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Dysarthria | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (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 |
| Epilepsy | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (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 |
| Hemiparesis | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (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 |
| Optic neuritis | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 1 / 91 (1.10%) | 0 / 93 (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 |

| | | | |
|---|----------------|----------------|----------------|
| Spinal cord disorder | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| 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 / 90 (0.00%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Deficiency anaemia | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 1 / 91 (1.10%) | 0 / 93 (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 |
| Eye disorders | | | |
| Scleritis | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (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 |
| Pancreatitis acute | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 1 / 91 (1.10%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Bile duct stone | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis acute | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Drug eruption | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (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 |
| Toxic skin eruption | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (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 |
| Musculoskeletal and connective tissue disorders | | | |
| Systemic lupus erythematosus | | | |
| subjects affected / exposed | 2 / 90 (2.22%) | 0 / 91 (0.00%) | 2 / 93 (2.15%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 0 / 91 (0.00%) | 0 / 93 (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 |
| Herpes zoster | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 90 (0.00%) | 0 / 91 (0.00%) | 1 / 93 (1.08%) |
| 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 chronic | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 1 / 91 (1.10%) | 0 / 93 (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 / 90 (0.00%) | 0 / 91 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------------|--|--|
| Serious adverse events | BMS-986165 12 mg QD | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 89 (7.87%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Squamous cell carcinoma of the vagina | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous incomplete | | | |

| | | | |
|--|----------------|--|--|
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Endometrial hyperplasia | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Uterine haemorrhage | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Forearm fracture | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Dysarthria | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hemiparesis | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Optic neuritis | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Seizure | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Spinal cord disorder | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|----------------|--|--|
| Anaemia | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Deficiency anaemia | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Scleritis | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Bile duct stone | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatitis acute | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Drug eruption | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Toxic skin eruption | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Systemic lupus erythematosus | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pyelonephritis chronic | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|----------------|--|--|
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 89 (1.12%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | Placebo | BMS-986165 3 mg BID | BMS-986165 6 mg BID |
|---|------------------|------------------------|------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 79 / 90 (87.78%) | 85 / 91 (93.41%) | 81 / 93 (87.10%) |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 3 / 90 (3.33%) | 4 / 91 (4.40%) | 3 / 93 (3.23%) |
| occurrences (all) | 3 | 4 | 3 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 15 / 90 (16.67%) | 7 / 91 (7.69%) | 8 / 93 (8.60%) |
| occurrences (all) | 20 | 8 | 9 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 5 / 90 (5.56%) | 4 / 91 (4.40%) | 8 / 93 (8.60%) |
| occurrences (all) | 6 | 4 | 8 |
| Nausea | | | |
| subjects affected / exposed | 8 / 90 (8.89%) | 6 / 91 (6.59%) | 5 / 93 (5.38%) |
| occurrences (all) | 8 | 8 | 6 |
| Vomiting | | | |
| subjects affected / exposed | 6 / 90 (6.67%) | 3 / 91 (3.30%) | 4 / 93 (4.30%) |
| occurrences (all) | 6 | 3 | 6 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 5 / 90 (5.56%) | 1 / 91 (1.10%) | 0 / 93 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 4 / 90 (4.44%) | 3 / 91 (3.30%) | 8 / 93 (8.60%) |
| occurrences (all) | 4 | 3 | 8 |
| Rash | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 90 (0.00%) 0 | 2 / 91 (2.20%) 3 | 3 / 93 (3.23%) 3 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 90 (1.11%) | 5 / 91 (5.49%) | 1 / 93 (1.08%) |
| occurrences (all) | 1 | 5 | 1 |
| Back pain | | | |
| subjects affected / exposed | 6 / 90 (6.67%) | 1 / 91 (1.10%) | 8 / 93 (8.60%) |
| occurrences (all) | 6 | 1 | 8 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 6 / 90 (6.67%) | 3 / 91 (3.30%) | 5 / 93 (5.38%) |
| occurrences (all) | 6 | 3 | 5 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 5 / 91 (5.49%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 9 | 1 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 11 / 90 (12.22%) | 8 / 91 (8.79%) | 13 / 93 (13.98%) |
| occurrences (all) | 21 | 11 | 19 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 90 (0.00%) | 4 / 91 (4.40%) | 4 / 93 (4.30%) |
| occurrences (all) | 0 | 7 | 8 |
| Pharyngitis | | | |
| subjects affected / exposed | 2 / 90 (2.22%) | 7 / 91 (7.69%) | 5 / 93 (5.38%) |
| occurrences (all) | 2 | 8 | 8 |
| Sinusitis | | | |
| subjects affected / exposed | 2 / 90 (2.22%) | 4 / 91 (4.40%) | 5 / 93 (5.38%) |
| occurrences (all) | 2 | 4 | 5 |
| Urinary tract infection | | | |
| subjects affected / exposed | 3 / 90 (3.33%) | 10 / 91 (10.99%) | 6 / 93 (6.45%) |
| occurrences (all) | 3 | 13 | 9 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 8 / 90 (8.89%) | 13 / 91 (14.29%) | 18 / 93 (19.35%) |
| occurrences (all) | 13 | 17 | 21 |

| | | | |
|-----------------------------------|---------------------|--|--|
| Non-serious adverse events | BMS-986165 12 mg QD | | |
|-----------------------------------|---------------------|--|--|

| | | | |
|---|---|--|--|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 73 / 89 (82.02%) | | |
| Vascular disorders Hypertension subjects affected / exposed occurrences (all) | 6 / 89 (6.74%) 6 | | |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 11 / 89 (12.36%) 19 | | |
| Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all) | 3 / 89 (3.37%) 4 4 / 89 (4.49%) 4 1 / 89 (1.12%) 1 | | |
| Respiratory, thoracic and mediastinal disorders Rhinorrhoea subjects affected / exposed occurrences (all) | 1 / 89 (1.12%) 1 | | |
| Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) | 7 / 89 (7.87%) 9 7 / 89 (7.87%) 8 | | |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain | 0 / 89 (0.00%) 0 | | |

| | | | |
|-----------------------------------|----------------|--|--|
| subjects affected / exposed | 2 / 89 (2.25%) | | |
| occurrences (all) | 2 | | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cystitis | | | |
| subjects affected / exposed | 2 / 89 (2.25%) | | |
| occurrences (all) | 2 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 8 / 89 (8.99%) | | |
| occurrences (all) | 8 | | |
| Oral herpes | | | |
| subjects affected / exposed | 5 / 89 (5.62%) | | |
| occurrences (all) | 5 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 2 / 89 (2.25%) | | |
| occurrences (all) | 3 | | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 89 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 6 / 89 (6.74%) | | |
| occurrences (all) | 7 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 8 / 89 (8.99%) | | |
| occurrences (all) | 12 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|--|
| 24 January 2018 | Updated endpoints, treatment frequency, and inclusion/exclusion criteria |
| 28 January 2019 | Updated endpoints and inclusion/exclusion criteria |
| 11 June 2019 | Updated endpoints and clarified inclusion criteria |
| 15 April 2020 | Updated contact information and endpoints |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported