



Clinical trial results:

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase 2 Study to Evaluate the Clinical Efficacy and Safety of BMS-986165 in Subjects With Moderate to Severe Psoriasis

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2016-002481-31 |
| Trial protocol | LV |
| Global end of trial date | 16 November 2017 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 01 December 2018 |
| First version publication date | 01 December 2018 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | IM011-011 |
|-----------------------|-----------|

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 | 16 November 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 November 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main study objectives were to compare the proportion of subjects with moderate to severe psoriasis in experiencing a 75% improvement as measured by reduction in Psoriasis Area and Severity Index (PASI) score after 12 weeks of treatment between doses of BMS-986165 and placebo and to assess the safety and tolerability of multiple oral doses of BMS-986165 in subjects with moderate to severe psoriasis.

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 subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 16 November 2016 |
| 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 | Germany: 32 |
| Country: Number of subjects enrolled | Latvia: 21 |
| Country: Number of subjects enrolled | Poland: 98 |
| Country: Number of subjects enrolled | Canada: 39 |
| Country: Number of subjects enrolled | United States: 37 |
| Country: Number of subjects enrolled | Australia: 16 |
| Country: Number of subjects enrolled | Mexico: 2 |
| Country: Number of subjects enrolled | Japan: 22 |
| Worldwide total number of subjects | 267 |
| EEA total number of subjects | 151 |

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) | 248 |
| From 65 to 84 years | 19 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

340 subjects were enrolled, 268 subjects were randomized in the study; One subject was randomized but did not receive study drug due to being lost to follow-up

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 |

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

Placebo for BMS-986165

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

Dosage and administration details:

0 mg

| | |
|------------------|--------------------|
| Arm title | BMS-986165 3MG QOD |
|------------------|--------------------|

Arm description:

BMS-986165 3mg capsules Every Other Day

| | |
|--|-----------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-986165 3 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

3mg Every Other Day

| | |
|------------------|-------------------|
| Arm title | BMS-986165 3MG QD |
|------------------|-------------------|

Arm description:

BMS-986165 3mg capsules Every Day

| | |
|--|-----------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-986165 3 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

3mg Every Day

| | |
|------------------|--------------------|
| Arm title | BMS-986165 3MG BID |
|------------------|--------------------|

Arm description:

BMS-986165 3mg capsules Twice Daily

| | |
|--|-----------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-986165 3 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

3mg Twice Daily

| | |
|------------------|--------------------|
| Arm title | BMS-986165 6MG BID |
|------------------|--------------------|

Arm description:

BMS-986165 6mg capsules Twice Daily

| | |
|--|-----------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-986165 6 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

6mg Twice Daily

| | |
|------------------|--------------------|
| Arm title | BMS-986165 12MG QD |
|------------------|--------------------|

Arm description:

BMS-986165 12mg capsules Every Day

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-986165 12 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

12 mg Every Day

| Number of subjects in period 1 | Placebo | BMS-986165 3MG QOD | BMS-986165 3MG QD |
|--|---------|--------------------|-------------------|
| Started | 45 | 44 | 44 |
| Completed | 31 | 34 | 36 |
| Not completed | 14 | 10 | 8 |
| Reason not provided by investigator | 1 | - | 1 |
| Subject request to discontinue treatment | 4 | 3 | 3 |

| | | | |
|------------------------------|---|---|---|
| Consent withdrawn by subject | 1 | 2 | - |
| Adverse event, non-fatal | 2 | 1 | 2 |
| Lost to follow-up | 1 | - | 1 |
| Poor/non-compliance | - | - | 1 |
| Lack of efficacy | 5 | 4 | - |

| Number of subjects in period 1 | BMS-986165 3MG BID | BMS-986165 6MG BID | BMS-986165 12MG QD |
|--|-------------------------------|-------------------------------|-------------------------------|
| Started | 45 | 45 | 44 |
| Completed | 42 | 39 | 42 |
| Not completed | 3 | 6 | 2 |
| Reason not provided by investigator | - | - | - |
| Subject request to discontinue treatment | - | 1 | - |
| Consent withdrawn by subject | 1 | - | - |
| Adverse event, non-fatal | 1 | 3 | 1 |
| Lost to follow-up | 1 | 2 | - |
| Poor/non-compliance | - | - | - |
| Lack of efficacy | - | - | 1 |

Baseline characteristics

| Reporting groups | |
|---|--------------------|
| Reporting group title | Placebo |
| Reporting group description: Placebo for BMS-986165 | |
| Reporting group title | BMS-986165 3MG QOD |
| Reporting group description: BMS-986165 3mg capsules Every Other Day | |
| Reporting group title | BMS-986165 3MG QD |
| Reporting group description: BMS-986165 3mg capsules Every Day | |
| Reporting group title | BMS-986165 3MG BID |
| Reporting group description: BMS-986165 3mg capsules Twice Daily | |
| Reporting group title | BMS-986165 6MG BID |
| Reporting group description: BMS-986165 6mg capsules Twice Daily | |
| Reporting group title | BMS-986165 12MG QD |
| Reporting group description: BMS-986165 12mg capsules Every Day | |

| Reporting group values | Placebo | BMS-986165 3MG QOD | BMS-986165 3MG QD |
|--|---------|--------------------|-------------------|
| Number of subjects | 45 | 44 | 44 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 43 | 44 | 40 |
| From 65-84 years | 2 | 0 | 4 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous Units: Years | | | |
| arithmetic mean | 46.4 | 41.0 | 45.0 |
| standard deviation | ± 11.93 | ± 11.8 | ± 13.77 |
| Sex: Female, Male Units: Subjects | | | |
| Female | 8 | 8 | 14 |
| Male | 37 | 36 | 30 |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 1 | 0 |
| Asian | 5 | 6 | 5 |

| | | | |
|---|----|----|----|
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 1 | 0 |
| White | 40 | 35 | 39 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 1 | 0 |

| Reporting group values | BMS-986165 3MG BID | BMS-986165 6MG BID | BMS-986165 12MG QD |
|---|-----------------------|-----------------------|-----------------------|
| Number of subjects | 45 | 45 | 44 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 38 | 44 | 39 |
| From 65-84 years | 7 | 1 | 5 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous Units: Years | | | |
| arithmetic mean | 45.6 | 42.8 | 46.6 |
| standard deviation | ± 15.10 | ± 12.90 | ± 11.62 |
| Sex: Female, Male Units: Subjects | | | |
| Female | 19 | 10 | 14 |
| Male | 26 | 35 | 30 |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 1 | 1 |
| Asian | 5 | 9 | 6 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 1 | 0 | 0 |
| White | 39 | 35 | 37 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |

| Reporting group values | Total | | |
|---|-------|--|--|
| Number of subjects | 267 | | |
| Age categorical Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 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) | 248 | | |
| From 65-84 years | 19 | | |
| 85 years and over | 0 | | |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 73 | | |
| Male | 194 | | |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 3 | | |
| Asian | 36 | | |
| Native Hawaiian or Other Pacific Islander | 0 | | |
| Black or African American | 2 | | |
| White | 225 | | |
| More than one race | 0 | | |
| Unknown or Not Reported | 1 | | |

End points

End points reporting groups

| | |
|---|--------------------|
| Reporting group title | Placebo |
| Reporting group description: Placebo for BMS-986165 | |
| Reporting group title | BMS-986165 3MG QOD |
| Reporting group description: BMS-986165 3mg capsules Every Other Day | |
| Reporting group title | BMS-986165 3MG QD |
| Reporting group description: BMS-986165 3mg capsules Every Day | |
| Reporting group title | BMS-986165 3MG BID |
| Reporting group description: BMS-986165 3mg capsules Twice Daily | |
| Reporting group title | BMS-986165 6MG BID |
| Reporting group description: BMS-986165 6mg capsules Twice Daily | |
| Reporting group title | BMS-986165 12MG QD |
| Reporting group description: BMS-986165 12mg capsules Every Day | |

Primary: The percentage of subjects with moderate to severe psoriasis experiencing a 75% improvement (reduction from baseline) in PASI score (PASI-75 response rate) on Day 85 (Week 12)

| | |
|--|---|
| End point title | The percentage of subjects with moderate to severe psoriasis experiencing a 75% improvement (reduction from baseline) in PASI score (PASI-75 response rate) on Day 85 (Week 12) |
| End point description: Psoriasis Area and Severity Index (PASI) 75 response: patients who achieved $\geq 75\%$ improvement (reduction) in PASI score compared to baseline were defined as PASI 75 responders. PASI scores can range from 0, corresponding to no signs of psoriasis up to theoretical maximum of 72.0, which means a higher PASI score reflects a higher psoriasis activity. | |
| End point type | Primary |
| End point timeframe: Day 1 to Day 85 | |

| End point values | Placebo | BMS-986165 3MG QOD | BMS-986165 3MG QD | BMS-986165 3MG BID |
|--|-------------------|--------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 45 | 44 | 44 | 45 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| % of subjects with PASI-75 response rate on Day 85 | 6.7 (1.4 to 18.3) | 9.1 (2.5 to 21.7) | 38.6 (24.4 to 54.5) | 68.9 (53.4 to 81.8) |

| End point values | BMS-986165 6MG BID | BMS-986165 12MG QD | | |
|---|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 45 | 44 | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| % of subjects with PASI-75 response rate on Day 85 | 66.7 (51.0 to 80.0) | 75.0 (59.7 to 86.8) | | |

Statistical analyses

| Statistical analysis title | P-value (Chi-Squared) BMS-986165 3MG QOD vs pbo |
|---|---|
| Comparison groups | Placebo v BMS-986165 3MG QOD |
| Number of subjects included in analysis | 89 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.4873 ^[1] |
| Method | Chi-squared |

Notes:

[1] - P-value is from the Fishers Exact if at least one cell count is <5. Otherwise, p-value is from the Chi-Square test.

| Statistical analysis title | P-value (Chi-Squared) BMS-986165 3MG QD vs pbo |
|---|--|
| Comparison groups | Placebo v BMS-986165 3MG QD |
| Number of subjects included in analysis | 89 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0003 ^[2] |
| Method | Chi-squared |

Notes:

[2] - P-value is from the Fishers Exact if at least one cell count is <5. Otherwise, p-value is from the Chi-Square test.

| Statistical analysis title | P-value (Chi-Squared) BMS-986165 3 MG BID vs pbo |
|---|--|
| Comparison groups | Placebo v BMS-986165 3MG BID |
| Number of subjects included in analysis | 90 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Chi-squared |

| Statistical analysis title | P-value (Chi-Squared) BMS-986165 6MG BID vs pbo |
|-----------------------------------|---|
| Comparison groups | Placebo v BMS-986165 6MG BID |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 90 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 ^[3] |
| Method | Chi-squared |

Notes:

[3] - P-value is from the Fishers Exact if at least one cell count is <5. Otherwise, p-value is from the Chi-Square test.

| | |
|---|---|
| Statistical analysis title | P-value (Chi-Squared) BMS-986165 12MG QD vs pbo |
| Comparison groups | Placebo v BMS-986165 12MG QD |
| Number of subjects included in analysis | 89 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 ^[4] |
| Method | Chi-squared |

Notes:

[4] - P-value is from the Fishers Exact if at least one cell count is <5. Otherwise, p-value is from the Chi-Square test.

Primary: Number of subjects with Adverse Events

| | |
|---|---|
| End point title | Number of subjects with Adverse Events ^[5] |
| End point description: The safety and tolerability of BMS-986195 as assessed by the number of subjects with adverse events (AEs); number of subjects with serious adverse events (SAEs); number of subjects with adverse events leading to discontinuation | |
| End point type | Primary |
| End point timeframe: Day 1 to day 115 | |

Notes:

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

Justification: Only summary statistics were planned for this endpoint

| End point values | Placebo | BMS-986165 3MG QOD | BMS-986165 3MG QD | BMS-986165 3MG BID |
|---|-----------------|-----------------------|----------------------|-----------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 45 | 44 | 44 | 45 |
| Units: Subjects | | | | |
| No. of subjects with SAEs | 1 | 1 | 1 | 1 |
| No. of subjects with AEs | 24 | 26 | 25 | 29 |
| No. of subjects who discontinued due to AEs | 2 | 1 | 2 | 1 |

| End point values | BMS-986165 6MG BID | BMS-986165 12MG QD | | |
|-----------------------------|-----------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 45 | 44 | | |
| Units: Subjects | | | | |
| No. of subjects with SAEs | 0 | 0 | | |
| No. of subjects with AEs | 36 | 34 | | |

| | | | | |
|---|---|---|--|--|
| No. of subjects who discontinued due to AEs | 3 | 1 | | |
|---|---|---|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects on Day 85 with PASI-50, PASI-90, PASI-100.

| | |
|---|---|
| End point title | Percentage of subjects on Day 85 with PASI-50, PASI-90, PASI-100. |
| End point description: | |
| Percentage of patients achieving Psoriasis Area and Severity Index (PASI) 50, PASI 90 and PASI 100 responses on Day 85. PASI 50 response: patients who achieved $\geq 50\%$ improvement (reduction) in PASI score compared to baseline were defined as PASI 50 responders. PASI 90 response: patients who achieved $\geq 90\%$ improvement (reduction) in PASI score compared to baseline were defined as PASI 90 responders. PASI 100 response: patients who achieved $\geq 100\%$ improvement (reduction) in PASI score compared to baseline were defined as PASI 100 responders. PASI scores can range from 0, corresponding to no signs of psoriasis up to theoretical maximum of 72.0, which means a higher PASI score reflects a higher psoriasis activity. | |
| End point type | Secondary |
| End point timeframe: | |
| Day 1 to Day 85 | |

| End point values | Placebo | BMS-986165 3MG QOD | BMS-986165 3MG QD | BMS-986165 3MG BID |
|---------------------------------------|---------------------|-----------------------|----------------------|-----------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 45 | 44 | 44 | 45 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| % of subjects with PASI-50 at Day 85 | 31.1 (18.2 to 46.6) | 43.2 (28.3 to 59.0) | 68.2 (52.4 to 81.4) | 91.1 (78.8 to 97.5) |
| % of subjects with PASI-90 at Day 85 | 2.2 (0.1 to 11.8) | 6.8 (1.4 to 18.7) | 15.9 (6.6 to 30.1) | 44.4 (29.6 to 60.0) |
| % of subjects with PASI-100 at Day 85 | 0 (0.0 to 7.9) | 2.3 (0.1 to 12.0) | 0 (0.0 to 8.0) | 8.9 (2.5 to 21.2) |

| End point values | BMS-986165 6MG BID | BMS-986165 12MG QD | | |
|--------------------------------------|-----------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 45 | 44 | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| % of subjects with PASI-50 at Day 85 | 77.8 (62.9 to 88.8) | 88.6 (75.4 to 96.2) | | |
| % of subjects with PASI-90 at Day 85 | 44.4 (29.6 to 60.0) | 43.2 (28.3 to 59.0) | | |

| | | | | |
|---------------------------------------|--------------------|---------------------|--|--|
| % of subjects with PASI-100 at Day 85 | 17.8 (8.0 to 32.1) | 25.0 (13.2 to 40.3) | | |
|---------------------------------------|--------------------|---------------------|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects on Day 85 with sPGA score of 0 or 1 (sPGA0/1 response rate).

| | |
|--|---|
| End point title | Percentage of subjects on Day 85 with sPGA score of 0 or 1 (sPGA0/1 response rate). |
| End point description: | |
| Percentage of subjects achieving a clear (0) or almost clear (1) status on the Static Physician Global Assessment (sPGA) on Day 85. This index evaluates the physician's global assessment of the participant's psoriasis based on severity of induration, scaling, and erythema. The assessment was scored on a scale of 0 to 5, where 0 = clear, with no evidence of plaque elevation, erythema, or scale, and 5 = severe induration, erythema, and scaling. | |
| End point type | Secondary |
| End point timeframe: | |
| Day 1 to Day 85 | |

| End point values | Placebo | BMS-986165 3MG QOD | BMS-986165 3MG QD | BMS-986165 3MG BID |
|--|-------------------|-----------------------|----------------------|-----------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 45 | 44 | 44 | 45 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| % of subjects on Day 85 with sPGA 0/1 response | 6.7 (1.4 to 18.3) | 20.5 (9.8 to 35.3) | 38.6 (24.4 to 54.5) | 75.6 (60.5 to 87.1) |

| End point values | BMS-986165 6MG BID | BMS-986165 12MG QD | | |
|--|-----------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 45 | 44 | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| % of subjects on Day 85 with sPGA 0/1 response | 64.4 (48.8 to 78.1) | 75.0 (59.7 to 86.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in DLQI scores on Day 85

| | |
|-----------------|---|
| End point title | Change from baseline in DLQI scores on Day 85 |
|-----------------|---|

End point description:

The DLQI is a subject reported quality of life index which consists of 10 questions concerning symptoms and feelings, daily activities, leisure, work, school, personal relationships, and treatment during the last week. Each question is scored on a scale of 0 to 3 by a tick box: "not at all", "a little", "a lot", or "very much". The scores are summed, giving a range from 0 (no impairment of life quality) to 30 (maximum impairment)

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

End point timeframe:

Day 1 to Day 85

| End point values | Placebo | BMS-986165 3MG QOD | BMS-986165 3MG QD | BMS-986165 3MG BID |
|---|------------------------|------------------------|------------------------|-------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 38 | 41 | 43 |
| Units: Score | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Change from baseline in DLQI scores on Day 85 | -2.85 (-4.33 to -1.37) | -3.76 (-5.15 to -2.38) | -6.07 (-8.07 to -4.08) | -9.67 (-11.42 to -7.93) |

| End point values | BMS-986165 6MG BID | BMS-986165 12MG QD | | |
|---|-------------------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 40 | 43 | | |
| Units: Score | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Change from baseline in DLQI scores on Day 85 | -8.38 (-10.72 to -6.03) | -10.16 (-12.27 to -8.06) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in BSA on Day 85

| | |
|-----------------|---------------------------------------|
| End point title | Change from baseline in BSA on Day 85 |
|-----------------|---------------------------------------|

End point description:

Measurement of psoriasis body surface area (BSA) involvement is estimated using the handprint method with the size of a patient's handprint representing ~1% of body surface area involved. The total BSA = 100% with breakdown by body region as follows: head and neck = 10% (10 handprints), upper extremities = 20% (20 handprints), trunk including axillae and groin = 30% (30 handprints), lower extremities including buttocks = 40% (40 handprints). A decrease from Baseline indicates improvement. Change from Baseline was calculated as Baseline score - Day 85 score; a positive change from Baseline therefore indicates improvement.

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

End point timeframe:

Day 1 to Day 85

| End point values | Placebo | BMS-986165 3MG QOD | BMS-986165 3MG QD | BMS-986165 3MG BID |
|--|----------------------------|---------------------------|-----------------------------|------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 34 | 38 | 41 | 43 |
| Units: Percentage | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Change from baseline in BSA on Day 85 | -7.71 (-11.88 to -3.54) | -5.50 (-8.17 to -2.83) | -12.59 (-18.28 to -6.89) | -18.60 (-23.69 to -13.52) |

| End point values | BMS-986165 6MG BID | BMS-986165 12MG QD | | |
|--|------------------------------|------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 40 | 43 | | |
| Units: Percentage | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Change from baseline in BSA on Day 85 | -17.23 (-20.85 to -13.60) | -15.16 (-18.64 to -11.69) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Trough observed plasma concentration of BMS-986165 (C_{trough})

| | |
|-----------------|--|
| End point title | Trough observed plasma concentration of BMS-986165 (C _{trough}) ^[6] |
|-----------------|--|

End point description:

Pharmacokinetics of BMS-986165 were derived from plasma concentration versus time data. C_{trough}= Trough observed plasma concentration

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

End point timeframe:

Days 8, 15, 29, 57, 85

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only summary statistics were planned for this endpoint

| End point values | BMS-986165 3MG QOD | BMS-986165 3MG QD | BMS-986165 3MG BID | BMS-986165 6MG BID |
|--------------------------------------|-----------------------|----------------------|-----------------------|-----------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 44 | 44 | 44 | 45 |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Ctrough of BMS-986165 | 2.024 (± 3.7061) | 3.145 (± 3.1588) | 14.819 (± 9.1410) | 26.257 (± 14.6483) |

| End point values | BMS-986165 12MG QD | | | |
|--------------------------------------|-----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 44 | | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Ctrough of BMS-986165 | 17.824 (± 22.7536) | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

First dose of study therapy and within 30 days of the last dose.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 20.0 |
|--------------------|------|

Reporting groups

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

Reporting group description:

Subjects received placebo capsules orally for 12 weeks.

| | |
|-----------------------|--------------|
| Reporting group title | BMS 3 mg QOD |
|-----------------------|--------------|

Reporting group description:

Subjects received BMS-986165 3 milligram (mg) capsules orally once every other day (QOD) for 12 weeks.

| | |
|-----------------------|-------------|
| Reporting group title | BMS 3 mg QD |
|-----------------------|-------------|

Reporting group description:

Subjects received BMS-986165 3 mg capsules orally once daily (QD) for 12 weeks.

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

Reporting group description:

Subjects received BMS-986165 3 mg capsules orally twice daily (BID) for 12 weeks.

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

Reporting group description:

Subjects received BMS-986165 6 mg capsules orally BID for 12 weeks.

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

Reporting group description:

Subjects received BMS-986165 12 mg capsules orally QD for 12 weeks.

| Serious adverse events | Placebo | BMS 3 mg QOD | BMS 3 mg QD |
|---|----------------|----------------|----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 1 / 44 (2.27%) | 1 / 44 (2.27%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Eye injury | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Dizziness | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| 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 | | | |
| Haemorrhagic anaemia | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 1 / 44 (2.27%) | 0 / 44 (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 |

| Serious adverse events | BMS 3 mg BID | BMS 6 mg BID | BMS 12 mg QD |
|---|---------------------|---------------------|---------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 45 (0.00%) | 0 / 44 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Eye injury | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 45 (0.00%) | 0 / 44 (0.00%) |
| 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 | | | |
| Dizziness | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 45 (0.00%) | 0 / 44 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|----------------|----------------|----------------|
| Haemorrhagic anaemia | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 45 (0.00%) | 0 / 44 (0.00%) |
| 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 | | | |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 45 (0.00%) | 0 / 44 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 45 (0.00%) | 0 / 44 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | Placebo | BMS 3 mg QOD | BMS 3 mg QD |
|---|------------------|------------------|------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 12 / 45 (26.67%) | 14 / 44 (31.82%) | 18 / 44 (40.91%) |
| Investigations | | | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 44 (0.00%) | 1 / 44 (2.27%) |
| occurrences (all) | 1 | 0 | 1 |
| Blood immunoglobulin E increased | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 3 / 44 (6.82%) | 2 / 44 (4.55%) |
| occurrences (all) | 1 | 3 | 2 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 2 / 45 (4.44%) | 4 / 44 (9.09%) | 4 / 44 (9.09%) |
| occurrences (all) | 2 | 4 | 5 |
| Gastrointestinal disorders | | | |
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 44 (0.00%) | 0 / 44 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |

| | | | |
|---|---------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 2 | 1 / 44 (2.27%) 2 | 1 / 44 (2.27%) 1 |
| Nausea subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 2 | 4 / 44 (9.09%) 4 | 0 / 44 (0.00%) 0 |
| Toothache subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 1 | 1 / 44 (2.27%) 1 | 1 / 44 (2.27%) 1 |
| Skin and subcutaneous tissue disorders | | | |
| Acne subjects affected / exposed occurrences (all) | 0 / 45 (0.00%) 0 | 1 / 44 (2.27%) 1 | 0 / 44 (0.00%) 0 |
| Pruritus subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 2 | 0 / 44 (0.00%) 0 | 1 / 44 (2.27%) 1 |
| Psoriasis subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 2 | 1 / 44 (2.27%) 1 | 3 / 44 (6.82%) 3 |
| Infections and infestations | | | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 2 | 1 / 44 (2.27%) 1 | 5 / 44 (11.36%) 6 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 45 (0.00%) 0 | 2 / 44 (4.55%) 2 | 3 / 44 (6.82%) 3 |

| Non-serious adverse events | BMS 3 mg BID | BMS 6 mg BID | BMS 12 mg QD |
|--|---------------------|---------------------|----------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 15 / 45 (33.33%) | 25 / 45 (55.56%) | 18 / 44 (40.91%) |
| Investigations | | | |
| Blood creatine phosphokinase increased subjects affected / exposed occurrences (all) | 0 / 45 (0.00%) 0 | 3 / 45 (6.67%) 3 | 5 / 44 (11.36%) 6 |
| Blood immunoglobulin E increased subjects affected / exposed occurrences (all) | 0 / 45 (0.00%) 0 | 2 / 45 (4.44%) 2 | 2 / 44 (4.55%) 2 |
| Nervous system disorders | | | |

| | | | |
|---|----------------------|----------------------|---------------------|
| Headache subjects affected / exposed occurrences (all) | 3 / 45 (6.67%) 3 | 3 / 45 (6.67%) 3 | 2 / 44 (4.55%) 2 |
| Gastrointestinal disorders | | | |
| Aphthous ulcer subjects affected / exposed occurrences (all) | 3 / 45 (6.67%) 3 | 0 / 45 (0.00%) 0 | 1 / 44 (2.27%) 1 |
| Diarrhoea subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 3 | 2 / 45 (4.44%) 2 | 4 / 44 (9.09%) 5 |
| Nausea subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 1 | 1 / 45 (2.22%) 1 | 2 / 44 (4.55%) 2 |
| Toothache subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 1 | 3 / 45 (6.67%) 3 | 1 / 44 (2.27%) 1 |
| Skin and subcutaneous tissue disorders | | | |
| Acne subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 1 | 2 / 45 (4.44%) 2 | 4 / 44 (9.09%) 4 |
| Pruritus subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 1 | 3 / 45 (6.67%) 3 | 2 / 44 (4.55%) 2 |
| Psoriasis subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 2 | 0 / 45 (0.00%) 0 | 0 / 44 (0.00%) 0 |
| Infections and infestations | | | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 5 / 45 (11.11%) 6 | 7 / 45 (15.56%) 8 | 3 / 44 (6.82%) 3 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 2 | 4 / 45 (8.89%) 4 | 1 / 44 (2.27%) 1 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

| |
|---|
| The limitations of this phase 2 trial include its small sample size and short duration; these results warrant confirmation in a larger trial of longer duration |
|---|

Notes: