



## Clinical trial results:

### A Multi-Center, Randomized, Double-Blind, Placebo- and Active Comparator-Controlled Phase 3 Study with Randomized Withdrawal and Retreatment to Evaluate the Efficacy and Safety of BMS-986165 in Subjects with Moderate-to-Severe Plaque Psoriasis

#### Summary

|                          |                         |
|--------------------------|-------------------------|
| EudraCT number           | 2018-001925-24          |
| Trial protocol           | GB FR CZ ES HU PL FI IT |
| Global end of trial date | 30 November 2020        |

#### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1 (current)    |
| This version publication date  | 25 October 2022 |
| First version publication date | 25 October 2022 |

#### Trial information

##### Trial identification

|                       |           |
|-----------------------|-----------|
| Sponsor protocol code | IM011-047 |
|-----------------------|-----------|

##### 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                       | 22 December 2020 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 30 November 2020 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

Assess whether BMS-986165 is superior to placebo at Week 16 in the treatment of subjects with moderate-to severe plaque 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 participants were followed.

Background therapy: -

Evidence for comparator: -

|   |              |
|---|--------------|
| Actual start date of recruitment                          | 26 July 2018 |
| 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 | Australia: 58      |
| Country: Number of subjects enrolled | Canada: 95         |
| Country: Number of subjects enrolled | Czechia: 60        |
| Country: Number of subjects enrolled | Finland: 9         |
| Country: Number of subjects enrolled | France: 10         |
| Country: Number of subjects enrolled | Germany: 34        |
| Country: Number of subjects enrolled | Hungary: 68        |
| Country: Number of subjects enrolled | Israel: 5          |
| Country: Number of subjects enrolled | New Zealand: 7     |
| Country: Number of subjects enrolled | Poland: 267        |
| Country: Number of subjects enrolled | Puerto Rico: 7     |
| Country: Number of subjects enrolled | Spain: 16          |
| Country: Number of subjects enrolled | Sweden: 15         |
| Country: Number of subjects enrolled | United Kingdom: 47 |
| Country: Number of subjects enrolled | United States: 322 |
| Worldwide total number of subjects   | 1020               |
| EEA total number of subjects         | 479                |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|---|-----|
| 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)                      | 912 |
| From 65 to 84 years                       | 108 |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

1020 participants randomized and 1018 treated. 1 Participant stopped treatment after Week 16 and re-entered in treatment period Week 24-52.

### Period 1

|                              |                                       |
|------------------------------|---------------------------------------|
| Period 1 title               | Pre-treatment                         |
| Is this the baseline period? | Yes                                   |
| Allocation method            | Randomised - controlled               |
| Blinding used                | Double blind                          |
| Roles blinded                | Investigator, Monitor, Carer, Subject |

### Arms

|                              |            |
|------------------------------|------------|
| Are arms mutually exclusive? | Yes        |
| <b>Arm title</b>             | BMS-986165 |

Arm description:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.

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

Dosage and administration details:

6 mg daily

|                  |         |
|------------------|---------|
| <b>Arm title</b> | Placebo |
|------------------|---------|

Arm description:

Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.

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

Dosage and administration details:

Placebo to match

|                  |            |
|------------------|------------|
| <b>Arm title</b> | Apremilast |
|------------------|------------|

Arm description:

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.

|          |                   |
|----------|-------------------|
| Arm type | Active comparator |
|----------|-------------------|

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

Dosage and administration details:

10 mg used for titration day 1 through day 3 morning dose. 20 mg used for titration day 3 through day 5 morning dose. 30 mg from day 5 evening dose onwards.

| Number of subjects in period 1 | BMS-986165 | Placebo | Apremilast |
|--------------------------------|------------|---------|------------|
| Started                        | 511        | 255     | 254        |
| Completed                      | 510        | 254     | 254        |
| Not completed                  | 1          | 1       | 0          |
| Randomized but not treated     | 1          | 1       | -          |

## Period 2

|                              |                                       |
|------------------------------|---------------------------------------|
| Period 2 title               | Treatment Week 0 - Week 16            |
| Is this the baseline period? | No                                    |
| Allocation method            | Randomised - controlled               |
| Blinding used                | Double blind                          |
| Roles blinded                | Subject, Investigator, Monitor, Carer |

## Arms

|                              |            |
|------------------------------|------------|
| Are arms mutually exclusive? | Yes        |
| <b>Arm title</b>             | BMS-986165 |

Arm description:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.

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

Dosage and administration details:

6 mg daily

|                  |         |
|------------------|---------|
| <b>Arm title</b> | Placebo |
|------------------|---------|

Arm description:

Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.

|          |         |
|----------|---------|
| Arm type | Placebo |
|----------|---------|

|  |            |
|--|------------|
| Investigational medicinal product name | Placebo    |
| Investigational medicinal product code |            |
| Other name                             |            |
| Pharmaceutical forms                   | Tablet     |
| Routes of administration               | Oral use   |
| Dosage and administration details:     |            |
| Placebo to match                       |            |
| <b>Arm title</b>                       | Apremilast |

**Arm description:**

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.

|  |                   |
|--|-------------------|
| Arm type                               | Active comparator |
| Investigational medicinal product name | Apremalist        |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Tablet            |
| Routes of administration               | Oral use          |

**Dosage and administration details:**

10 mg used for titration day 1 through day 3 morning dose. 20 mg used for titration day 3 through day 5 morning dose. 30 mg from day 5 evening dose onwards.

| <b>Number of subjects in period 2</b> | BMS-986165 | Placebo | Apremilast |
|---------------------------------------|------------|---------|------------|
| Started                               | 510        | 254     | 254        |
| Completed                             | 456        | 212     | 217        |
| Not completed                         | 54         | 42      | 37         |
| Adverse event, serious fatal          | -          | -       | 1          |
| Consent withdrawn by subject          | 14         | 9       | 9          |
| Adverse event, non-fatal              | 11         | 7       | 12         |
| Pregnancy                             | -          | -       | 1          |
| Non-compliance with protocol          | 5          | 2       | 1          |
| Other reasons                         | 13         | 9       | 7          |
| Lost to follow-up                     | 5          | 6       | 2          |
| Lack of efficacy                      | 6          | 9       | 4          |

**Period 3**

|                              |                             |
|------------------------------|-----------------------------|
| Period 3 title               | Treatment Week 16 - Week 24 |
| Is this the baseline period? | No                          |
| Allocation method            | Randomised - controlled     |
| Blinding used                | Double blind                |

|   |                                       |
|---|---------------------------------------|
| Roles blinded   | Subject, Investigator, Monitor, Carer |
| <b>Arms</b>   |                                       |
| Are arms mutually exclusive?  | Yes                                   |
| <b>Arm title</b>  | BMS-986165                            |
| Arm description:  |                                       |
| Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24. |                                       |
| Arm type  | Experimental                          |
| Investigational medicinal product name  | BMS-986165                            |
| Investigational medicinal product code  |                                       |
| Other name  |                                       |
| Pharmaceutical forms  | Tablet                                |
| Routes of administration  | Oral use                              |
| Dosage and administration details:  |                                       |
| 6 mg daily  |                                       |
| <b>Arm title</b>  | Apremilast                            |

|   |                   |
|---|-------------------|
| Arm description:  |                   |
| Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24. |                   |
| Arm type  | Active comparator |
| Investigational medicinal product name  | Apremalist        |
| Investigational medicinal product code  |                   |
| Other name  |                   |
| Pharmaceutical forms  | Tablet            |
| Routes of administration  | Oral use          |
| Dosage and administration details:  |                   |
| 10 mg used for titration day 1 through day 3 morning dose. 20 mg used for titration day 3 through day 5 morning dose. 30 mg from day 5 evening dose onwards.  |                   |

| <b>Number of subjects in period 3</b>   | BMS-986165       | Apremilast       |
|---|------------------|------------------|
| Started                                 | 668              | 217              |
| Discontinued (re-entered at Week 24-52) | 1 <sup>[1]</sup> | 0 <sup>[2]</sup> |
| Completed                               | 643              | 208              |
| Not completed                           | 25               | 9                |
| Consent withdrawn by subject            | 2                | 1                |
| Adverse event, non-fatal                | 7                | 2                |
| Pregnancy                               | 1                | 1                |
| Non-compliance with protocol            | 3                | 1                |
| Other reasons                           | 2                | 3                |
| Lost to follow-up                       | 2                | -                |
| Lack of efficacy                        | 8                | 1                |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 1 Participant stopped treatment after week 16 and re-entered in treatment period Week 24-52

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 1 Participant stopped treatment after week 16 and re-entered in treatment period Week 24-52.

#### Period 4

|                              |                                       |
|------------------------------|---------------------------------------|
| Period 4 title               | Treatment Week 24 - Week 52           |
| Is this the baseline period? | No                                    |
| Allocation method            | Randomised - controlled               |
| Blinding used                | Double blind                          |
| Roles blinded                | Subject, Investigator, Monitor, Carer |

#### Arms

|                              |            |
|------------------------------|------------|
| Are arms mutually exclusive? | Yes        |
| <b>Arm title</b>             | BMS-986165 |

Arm description:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.

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

Dosage and administration details:

6 mg daily

|                  |         |
|------------------|---------|
| <b>Arm title</b> | Placebo |
|------------------|---------|

Arm description:

Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.

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

Dosage and administration details:

Placebo to match



| <b>Number of subjects in period 4</b> | <b>BMS-986165</b> | <b>Placebo</b> |
|---------------------------------------|-------------------|----------------|
| Started                               | 604               | 247            |
| Completed                             | 535               | 214            |
| Not completed                         | 69                | 33             |
| Consent withdrawn by subject          | 8                 | 6              |
| Adverse event, non-fatal              | 14                | 7              |
| Pregnancy                             | -                 | 1              |
| Non-compliance with protocol          | 2                 | -              |
| Other reasons                         | 28                | 7              |
| Lost to follow-up                     | 9                 | 4              |
| Lack of efficacy                      | 8                 | 8              |

## Baseline characteristics

### Reporting groups

|                       |            |
|-----------------------|------------|
| Reporting group title | BMS-986165 |
|-----------------------|------------|

Reporting group description:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.

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

Reporting group description:

Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.

|                       |            |
|-----------------------|------------|
| Reporting group title | Apremilast |
|-----------------------|------------|

Reporting group description:

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.

| Reporting group values                                | BMS-986165 | Placebo | Apremilast |
|---|------------|---------|------------|
| Number of subjects                                    | 511        | 255     | 254        |
| Age categorical<br>Units: Subjects                    |            |         |            |
| In utero  | 0          | 0       | 0          |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0          | 0       | 0          |
| Newborns (0-27 days)                                  | 0          | 0       | 0          |
| Infants and toddlers (28 days-23<br>months)           | 0          | 0       | 0          |
| Children (2-11 years)                                 | 0          | 0       | 0          |
| Adolescents (12-17 years)                             | 0          | 0       | 0          |
| Adults (18-64 years)                                  | 457        | 229     | 226        |
| From 65-84 years                                      | 54         | 26      | 28         |
| 85 years and over                                     | 0          | 0       | 0          |
| Age Continuous<br>Units: Years                        |            |         |            |
| median  | 46.9       | 47.3    | 46.4       |
| standard deviation                                    | ± 13.37    | ± 13.57 | ± 13.28    |
| Sex: Female, Male<br>Units: Participants              |            |         |            |
| Female  | 175        | 74      | 97         |
| Male  | 336        | 181     | 157        |
| Ethnicity (NIH/OMB)<br>Units: Subjects                |            |         |            |
| Hispanic or Latino                                    | 58         | 29      | 29         |
| Not Hispanic or Latino                                | 445        | 226     | 223        |
| Unknown or Not Reported                               | 8          | 0       | 2          |
| Race/Ethnicity, Customized<br>Units: Subjects         |            |         |            |
| White   | 474        | 232     | 229        |

|   |    |   |    |
|---|----|---|----|
| Black or African American                 | 8  | 9 | 9  |
| Asian                                     | 24 | 8 | 12 |
| American Indian or Alaska Native          | 2  | 2 | 3  |
| Native Hawaiian or Other Pacific Islander | 0  | 0 | 0  |
| Other                                     | 3  | 4 | 1  |

|  |       |  |  |
|--|-------|--|--|
| <b>Reporting group values</b>                      | Total |  |  |
| Number of subjects                                 | 1020  |  |  |
| 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)                               | 912   |  |  |
| From 65-84 years                                   | 108   |  |  |
| 85 years and over                                  | 0     |  |  |
| Age Continuous                                     |       |  |  |
| Units: Years                                       |       |  |  |
| median   |       |  |  |
| standard deviation                                 | -     |  |  |
| Sex: Female, Male                                  |       |  |  |
| Units: Participants                                |       |  |  |
| Female   | 346   |  |  |
| Male   | 674   |  |  |
| Ethnicity (NIH/OMB)                                |       |  |  |
| Units: Subjects                                    |       |  |  |
| Hispanic or Latino                                 | 116   |  |  |
| Not Hispanic or Latino                             | 894   |  |  |
| Unknown or Not Reported                            | 10    |  |  |
| Race/Ethnicity, Customized                         |       |  |  |
| Units: Subjects                                    |       |  |  |
| White  | 935   |  |  |
| Black or African American                          | 26    |  |  |
| Asian  | 44    |  |  |
| American Indian or Alaska Native                   | 7     |  |  |
| Native Hawaiian or Other Pacific Islander          | 0     |  |  |
| Other  | 8     |  |  |

## End points

### End points reporting groups

|   |            |
|---|------------|
| Reporting group title   | BMS-986165 |
| Reporting group description:<br>Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.   |            |
| Reporting group title   | Placebo    |
| Reporting group description:<br>Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.   |            |
| Reporting group title   | Apremilast |
| Reporting group description:<br>Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24. |            |
| Reporting group title   | BMS-986165 |
| Reporting group description:<br>Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.   |            |
| Reporting group title   | Placebo    |
| Reporting group description:<br>Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.   |            |
| Reporting group title   | Apremilast |
| Reporting group description:<br>Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24. |            |
| Reporting group title   | BMS-986165 |
| Reporting group description:<br>Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.   |            |
| Reporting group title   | Apremilast |
| Reporting group description:<br>Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24. |            |
| Reporting group title   | BMS-986165 |
| Reporting group description:<br>Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.   |            |
| Reporting group title   | Placebo    |
| Reporting group description:<br>Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.   |            |

**Primary: The Number of Participants with a static Physician's Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (sPGA 0/1)**

|                 |   |
|-----------------|---|
| End point title | The Number of Participants with a static Physician's Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (sPGA 0/1) <sup>[1]</sup> |
|-----------------|---|

End point description:

The sPGA is a 5-point scale average assessment of all psoriatic lesions graded for erythema, scale, and induration. The sPGA measure determines psoriasis severity at a single point in time (without taking into account the baseline disease condition) as: clear (0), almost clear (1), mild (2), moderate (3), or severe (4). The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. The higher sPGA score denotes to more severe disease activity. sPGA 0/1 is the response as a number of participants who experience a sPGA score that determines psoriasis severity as 0 or 1 with at least a 2-point improvement from baseline using the non-responder imputation (NRI) method.

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Week 16

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 end point

| End point values            | BMS-986165      | Placebo         |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 511             | 255             |  |  |
| Units: Participants         | 253             | 22              |  |  |

**Statistical analyses**

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Placebo    |
| Number of subjects included in analysis | 766                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 10.55                   |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 6.54                    |
| upper limit                             | 17                      |

**Primary: The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (PASI 75)**

|                 |   |
|-----------------|---|
| End point title | The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (PASI 75) <sup>[2]</sup> |
|-----------------|---|

End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 75 is the response as a number of participants who experience at least a 75% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Baseline and Week 16

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 end point

| End point values            | BMS-986165      | Placebo         |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 511             | 255             |  |  |
| Units: Participants         | 271             | 24              |  |  |

**Statistical analyses**

| Statistical analysis title              | Odds Ratio              |
|---|-------------------------|
| Comparison groups                       | BMS-986165 v Placebo    |
| Number of subjects included in analysis | 766                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 10.49                   |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 6.65                    |
| upper limit                             | 16.55                   |

## Secondary: The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index Score at Week 16 (PASI 90)

|                 |  |
|-----------------|--|
| End point title | The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index Score at Week 16 (PASI 90) |
|-----------------|--|

### End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 90 is the response as a number of participants who experience at least a 90% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

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

### End point timeframe:

Baseline and Week 16

| End point values            | BMS-986165      | Placebo         | Apremilast      |  |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Subject group type          | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed | 511             | 255             | 254             |  |
| Units: Participants         | 138             | 7               | 46              |  |

## Statistical analyses

| Statistical analysis title              | Odds Ratio              |
|---|-------------------------|
| Comparison groups                       | BMS-986165 v Placebo    |
| Number of subjects included in analysis | 766                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 11.42                   |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 5.45                    |
| upper limit                             | 23.93                   |

| Statistical analysis title | Odds Ratio              |
|----------------------------|-------------------------|
| Comparison groups          | BMS-986165 v Apremilast |

|   |                         |
|---|-------------------------|
| Number of subjects included in analysis | 765                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.0046                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 1.74                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.18                    |
| upper limit                             | 2.56                    |

### Secondary: The Number of Participants who Achieve a 100% Improvement from Baseline in the Psoriasis Area and Severity Index Score at Week 16 (PASI 100)

|                 |  |
|-----------------|--|
| End point title | The Number of Participants who Achieve a 100% Improvement from Baseline in the Psoriasis Area and Severity Index Score at Week 16 (PASI 100) |
|-----------------|--|

End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 100 is the response as a number of participants who experience at least a 100% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

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

End point timeframe:

Baseline and Week 16

| End point values            | BMS-986165      | Placebo         | Apremilast      |  |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Subject group type          | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed | 511             | 255             | 254             |  |
| Units: Participants         | 52              | 3               | 11              |  |

### Statistical analyses

|                            |                      |
|----------------------------|----------------------|
| Statistical analysis title | Odds Ratio           |
| Comparison groups          | BMS-986165 v Placebo |



|   |                         |
|---|-------------------------|
| Number of subjects included in analysis | 766                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.001                 |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 9.21                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 2.89                    |
| upper limit                             | 29.4                    |

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 765                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.0051                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 2.55                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.3                     |
| upper limit                             | 5                       |

## Secondary: The Number of Participants with a static Physician Global Assessment Score of 0 at Week 16 (sPGA 0)

|                 |   |
|-----------------|---|
| End point title | The Number of Participants with a static Physician Global Assessment Score of 0 at Week 16 (sPGA 0) |
|-----------------|---|

### End point description:

The sPGA is a 5-point scale average assessment of all psoriatic lesions graded for erythema, scale, and induration. The sPGA measure determines psoriasis severity at a single point in time (without taking into account the baseline disease condition) as: clear (0), almost clear (1), mild (2), moderate (3), or severe (4). The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. sPGA 0 is the response as a number of participants who experience a sPGA score that determines psoriasis severity as 0 using the non-responder imputation (NRI) method.

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 16              |           |

| <b>End point values</b>     | BMS-986165      | Placebo         | Apremilast      |  |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Subject group type          | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed | 511             | 255             | 254             |  |
| Units: Participants         | 80              | 3               | 16              |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | Odds Ratio              |
|---|-------------------------|
| Comparison groups                       | BMS-986165 v Placebo    |
| Number of subjects included in analysis | 766                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 14.44                   |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 4.62                    |
| upper limit                             | 45.11                   |

| <b>Statistical analysis title</b>       | Odds Ratio              |
|---|-------------------------|
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 765                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.0002                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 2.85                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.61                    |
| upper limit                             | 5.03                    |

## Secondary: Change from Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score at Week 16

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score at Week 16 |
|-----------------|--|

### End point description:

The PSSD is an 11-item participant-reported instrument that assesses severity of symptoms and participant-observed signs commonly associated in plaque psoriasis. The PSSD assesses severity of 5 symptoms (itch, pain, stinging, burning, skin tightness) and 6 participant-observed signs (skin dryness,

cracking, scaling, shedding or flaking, redness, bleeding) using 0 to 10 numerical ratings. The severity of each item is rated on an 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable) where the symptoms summary score is derived from an average of the scores. A higher score indicates more severe disease. Baseline is defined as the measurement at the randomization visit (Week 0).

A modified baseline observation carried forward (mBOCF) approach will be used in participants with missing data. Missing values will have the last valid observation carried forward (including the baseline value as applicable).

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline and Week 16 |           |

| End point values                     | BMS-986165           | Placebo             | Apremilast           |  |
|--------------------------------------|----------------------|---------------------|----------------------|--|
| Subject group type                   | Reporting group      | Reporting group     | Reporting group      |  |
| Number of subjects analysed          | 466                  | 239                 | 233                  |  |
| Units: Score on a scale              |                      |                     |                      |  |
| arithmetic mean (standard deviation) | -28.9 ( $\pm$ 25.22) | -4.2 ( $\pm$ 19.58) | -21.5 ( $\pm$ 25.44) |  |

## Statistical analyses

|   |                            |
|---|----------------------------|
| <b>Statistical analysis title</b>       | ANCOVA                     |
| Comparison groups                       | BMS-986165 v Placebo       |
| Number of subjects included in analysis | 705                        |
| Analysis specification                  | Pre-specified              |
| Analysis type                           |                            |
| P-value                                 | < 0.0001                   |
| Method                                  | ANCOVA                     |
| Parameter estimate                      | Mean difference (net)      |
| Point estimate                          | -23.6                      |
| Confidence interval                     |                            |
| level                                   | 95 %                       |
| sides                                   | 2-sided                    |
| lower limit                             | -26.9                      |
| upper limit                             | -20.3                      |
| Variability estimate                    | Standard error of the mean |
| Dispersion value                        | 1.67                       |

|                                   |                         |
|-----------------------------------|-------------------------|
| <b>Statistical analysis title</b> | ANCOVA                  |
| Comparison groups                 | BMS-986165 v Apremilast |

|   |                            |
|---|----------------------------|
| Number of subjects included in analysis | 699                        |
| Analysis specification                  | Pre-specified              |
| Analysis type                           |                            |
| P-value                                 | < 0.0001                   |
| Method                                  | ANCOVA                     |
| Parameter estimate                      | Mean difference (net)      |
| Point estimate                          | -7.2                       |
| Confidence interval                     |                            |
| level                                   | 95 %                       |
| sides                                   | 2-sided                    |
| lower limit                             | -10.5                      |
| upper limit                             | -3.9                       |
| Variability estimate                    | Standard error of the mean |
| Dispersion value                        | 1.68                       |

## Secondary: Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score of 0 at Week 16

|                 |   |
|-----------------|---|
| End point title | Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score of 0 at Week 16 |
|-----------------|---|

### End point description:

Psoriasis Symptoms and Signs Diary (PSSD) is an 11-item participant-reported instrument that assesses severity of symptoms and participant-observed signs commonly associated in plaque psoriasis. The PSSD assesses severity of 5 symptoms (itch, pain, stinging, burning, skin tightness) and 6 participant-observed signs (skin dryness, cracking, scaling, shedding or flaking, redness, bleeding) using 0 to 10 numerical ratings. The severity of each item is rated on an 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable) where the symptoms summary score is derived from the average of the scores. A higher score indicates more severe disease. PSSD 0 is the response as a number of participants who experience a PSSD symptom score that determines psoriasis severity as 0 among participants with a baseline PSSD symptom score  $\geq 1$  using the non-responder imputation (NRI) method.

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

### End point timeframe:

Week 16

| End point values            | BMS-986165      | Placebo         | Apremilast      |  |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Subject group type          | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed | 466             | 238             | 232             |  |
| Units: Participants         | 35              | 3               | 10              |  |

## Statistical analyses

|                            |                      |
|----------------------------|----------------------|
| Statistical analysis title | Odds Ratio           |
| Comparison groups          | BMS-986165 v Placebo |

|   |                         |
|---|-------------------------|
| Number of subjects included in analysis | 704                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.0005                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 6.4                     |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.94                    |
| upper limit                             | 21.15                   |

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 698                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.0928                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 1.82                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 0.89                    |
| upper limit                             | 3.71                    |

### **Secondary: The Number of Participants with a Scalp Specific Physician's Global Assessment (ss-PGA) Score 0 or 1 at Week 16 (ss-PGA 0/1)**

|                 |  |
|-----------------|--|
| End point title | The Number of Participants with a Scalp Specific Physician's Global Assessment (ss-PGA) Score 0 or 1 at Week 16 (ss-PGA 0/1) |
|-----------------|--|

End point description:

The scalp specific Physician's Global Assessment (ss-PGA) evaluates scalp lesions in terms of clinical signs of redness, thickness, and scaliness and scored on the following 5-point ss-PGA scale: 0 = absence of disease, 1 = very mild disease, 2 = mild disease, 3 = moderate disease, 4 = severe disease. ss-PGA 0/1 is the response as a number of participants who experience a ss-PGA score of 0 or 1 with at least a 2-point improvement from baseline among participants with a baseline ss-PGA score  $\geq 3$ .

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 16              |           |

| <b>End point values</b>     | BMS-986165      | Placebo         | Apremilast      |  |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Subject group type          | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed | 305             | 173             | 166             |  |
| Units: Participants         | 182             | 30              | 61              |  |

## Statistical analyses

| <b>Statistical analysis title</b>       | Odds Ratio              |
|---|-------------------------|
| Comparison groups                       | BMS-986165 v Placebo    |
| Number of subjects included in analysis | 478                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 6.85                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 4.34                    |
| upper limit                             | 10.81                   |

| <b>Statistical analysis title</b>       | Odds Ratio              |
|---|-------------------------|
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 471                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 2.63                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.77                    |
| upper limit                             | 3.91                    |

## Secondary: The Number of Participants with a Dermatology Life Quality Index (DLQI) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (DLQI 0/1)

|                 |   |
|-----------------|---|
| End point title | The Number of Participants with a Dermatology Life Quality Index (DLQI) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (DLQI 0/1) <sup>[3]</sup> |
|-----------------|---|

### End point description:

The DLQI is a participant-reported quality of life index which consists of 10 questions concerning how

much skin problems affect 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 where 0 = not at all, 1 = a little, 2 = a lot, or 3 = very much. The scores are summed, giving a range from 0 (no impairment of life quality) to 30 (maximum impairment). DLQI 0/1 is the number of participants with a score of 0 or 1 among participants with a baseline DLQI score  $\geq 2$ .

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

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

End point timeframe:

Week 16

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 end point

| End point values            | BMS-986165      | Placebo         |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 495             | 246             |  |  |
| Units: Participants         | 186             | 24              |  |  |

## Statistical analyses

| Statistical analysis title              | Odds Ratio              |
|---|-------------------------|
| Comparison groups                       | BMS-986165 v Placebo    |
| Number of subjects included in analysis | 741                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 5.38                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 3.42                    |
| upper limit                             | 8.47                    |

## Secondary: The Number of Participants with a Physician Global Assessment- Fingernails (PGA-F) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (PGA-F 0/1)

|                 |   |
|-----------------|---|
| End point title | The Number of Participants with a Physician Global Assessment- Fingernails (PGA-F) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (PGA-F 0/1) <sup>[4]</sup> |
|-----------------|---|

End point description:

The Physician Global Assessment- Fingernails (PGA-F) evaluates the overall condition of the fingernails and is rated on a 5-point scale: 0 = clear, 1 = minimal, 2 = mild, 3 = moderate, and 4 = severe. PGA-F 0/1 is the response as a number of participants with a PGA-F score of 0 or 1 with at least a 2-point improvement from baseline among participants with a baseline PGA-F score  $\geq 3$ .

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 16              |           |

Notes:

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

Justification: Only pre-specified arms planned for this end point

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>     | BMS-986165      | Placebo         |  |  |
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 69              | 38              |  |  |
| Units: Participants         | 14              | 3               |  |  |

### Statistical analyses

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Placebo    |
| Number of subjects included in analysis | 107                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.0621                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 3.21                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 0.88                    |
| upper limit                             | 11.79                   |

### Secondary: The Number of Participants with a Palmoplantar Physician's Global Assessment (pp-PGA) Score of 0 or 1 at Week 16 (pp-PGA 0/1)

|                 |   |
|-----------------|---|
| End point title | The Number of Participants with a Palmoplantar Physician's Global Assessment (pp-PGA) Score of 0 or 1 at Week 16 (pp-PGA 0/1) |
|-----------------|---|

End point description:

The palmoplantar Physician's Global Assessment (pp-PGA) score evaluates palmoplantar (including finger and toe surfaces) psoriasis lesions based on overall severity by investigator, then scored on the following 5-point scale: 0 = clear; 1 = almost clear; 2 = mild; 3 = moderate; and 4 = severe. pp-PGA 0/1 is the number of participants with a score of 0 or 1 among participants with a baseline pp-PGA score  $\geq 3$ .

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 16              |           |



|                             |                 |                 |                 |  |
|-----------------------------|-----------------|-----------------|-----------------|--|
| <b>End point values</b>     | BMS-986165      | Placebo         | Apremilast      |  |
| Subject group type          | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed | 39              | 17              | 20              |  |
| Units: Participants         | 18              | 4               | 8               |  |

### Statistical analyses

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 59                      |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.3793                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 0.32                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 0.02                    |
| upper limit                             | 5.56                    |

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Placebo    |
| Number of subjects included in analysis | 56                      |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.6692                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 0.64                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 0.06                    |
| upper limit                             | 7.46                    |

**Secondary: The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 16 (PASI 75)**

|                 |  |
|-----------------|--|
| End point title | The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 16 (PASI 75) <sup>[5]</sup> |
|-----------------|--|

**End point description:**

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 75 is the response as a number of participants who experience at least a 75% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline and Week 16 |           |

**Notes:**

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

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>     | BMS-986165      | Apremilast      |  |  |
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 511             | 254             |  |  |
| Units: Participants         | 271             | 101             |  |  |

**Statistical analyses**

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 765                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.0004                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 1.76                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.29                    |
| upper limit                             | 2.41                    |

**Secondary: The Number of Participants with a static Physician Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 16 (sPGA 0/1)**

|                 |  |
|-----------------|--|
| End point title | The Number of Participants with a static Physician Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 16 (sPGA 0/1) <sup>[6]</sup> |
|-----------------|--|

End point description:

The sPGA is a 5-point scale average assessment of all psoriatic lesions graded for erythema, scale, and induration. The sPGA measure determines psoriasis severity at a single point in time (without taking into account the baseline disease condition) as: clear (0), almost clear (1), mild (2), moderate (3), or severe (4). The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. sPGA 0/1 is the number of participants with a sPGA score of 0 or 1 with at least a 2-point improvement from baseline.

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 16 or who have missing Week 16 endpoint data for any reason.

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

End point timeframe:

Week 16

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 pre-specified arms planned for this end point

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>     | BMS-986165      | Apremilast      |  |  |
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 511             | 254             |  |  |
| Units: Participants         | 253             | 86              |  |  |

## Statistical analyses

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 765                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 2.01                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.45                    |
| upper limit                             | 2.78                    |

## Secondary: Time to Relapse Until Week 52 Among Week 24 PASI 75 Responders

|                 |  |
|-----------------|--|
| End point title | Time to Relapse Until Week 52 Among Week 24 PASI 75 Responders |
|-----------------|--|

End point description:

Relapse is defined as 50% loss or greater of Week 24 PASI percent improvement from baseline.

The PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 -4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to

top of buttocks). PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. Note: 99999 = N/A (Insufficient number of participants with events)

|  |           |
|--|-----------|
| End point type   | Secondary |
| End point timeframe:                                   |           |
| From Week 24 to Week 52 (up to approximately 28 weeks) |           |

| End point values                 | BMS-986165             | Placebo                | Apremilast             |  |
|----------------------------------|------------------------|------------------------|------------------------|--|
| Subject group type               | Reporting group        | Reporting group        | Reporting group        |  |
| Number of subjects analysed      | 145                    | 150                    | 95                     |  |
| Units: Days                      |                        |                        |                        |  |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 197.0 (125.0 to 99999) |  |

## Statistical analyses

|   |                      |
|---|----------------------|
| Statistical analysis title              | Log Rank             |
| Comparison groups                       | BMS-986165 v Placebo |
| Number of subjects included in analysis | 295                  |
| Analysis specification                  | Pre-specified        |
| Analysis type                           |                      |
| P-value                                 | < 0.0001             |
| Method                                  | Logrank              |

## Secondary: The Number of Participants with a static Physician Global Assessment (sPGA) score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (sPGA 0/1)

|                 |  |
|-----------------|--|
| End point title | The Number of Participants with a static Physician Global Assessment (sPGA) score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (sPGA 0/1) <sup>[7]</sup> |
|-----------------|--|

### End point description:

The sPGA is a 5-point scale average assessment of all psoriatic lesions graded for erythema, scale, and induration. The sPGA measure determines psoriasis severity at a single point in time (without taking into account the baseline disease condition) as: clear (0), almost clear (1), mild (2), moderate (3), or severe (4). The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. sPGA 0/1 is the number of participants with a sPGA score of 0 or 1.

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 24 or who have missing Week 24 endpoint data for any reason.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 24              |           |

### Notes:

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

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>     | BMS-986165      | Apremilast      |  |  |
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 504             | 254             |  |  |
| Units: Participants         | 251             | 75              |  |  |

## Statistical analyses

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 758                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 2.47                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.78                    |
| upper limit                             | 3.43                    |

## Secondary: The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (PASI 75)

|                 |  |
|-----------------|--|
| End point title | The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (PASI 75) <sup>[8]</sup> |
|-----------------|--|

### End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 75 is the response as a number of participants who experience at least a 75% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 24 or who have missing Week 24 endpoint data for any reason.

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

### End point timeframe:

Baseline and Week 24

### Notes:

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

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>     | BMS-986165      | Apremilast      |  |  |
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 504             | 254             |  |  |
| Units: Participants         | 296             | 96              |  |  |

## Statistical analyses

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 758                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 2.44                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.78                    |
| upper limit                             | 3.36                    |

## Secondary: The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (PASI 90)

|                 |   |
|-----------------|---|
| End point title | The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (PASI 90) <sup>[9]</sup> |
|-----------------|---|

### End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 90 is the response as a number of participants who experience at least a 90% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) will be used for participants who: Discontinue treatment or study prior to Week 24 or who have missing Week 24 endpoint data for any reason.

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

### End point timeframe:

Baseline and Week 24

### Notes:

[9] - 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 end point

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>     | BMS-986165      | Apremilast      |  |  |
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 504             | 254             |  |  |
| Units: Participants         | 164             | 50              |  |  |

## Statistical analyses

|   |                         |
|---|-------------------------|
| <b>Statistical analysis title</b>       | Odds Ratio              |
| Comparison groups                       | BMS-986165 v Apremilast |
| Number of subjects included in analysis | 758                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | = 0.0001                |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Odds ratio (OR)         |
| Point estimate                          | 2.07                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | 1.43                    |
| upper limit                             | 3.01                    |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Participants were assessed for Death (all causes) from their first dose until the study was completed (up to approximately 60 weeks). SAEs and NSAEs were assessed from first dose to 30 days following last dose (up to approximately 56 weeks)

Adverse event reporting additional description:

The total number of subjects exposed represents all participants that received at least 1 dose of study medication.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 23.1 |
|--------------------|------|

### Reporting groups

|                       |                                   |
|-----------------------|-----------------------------------|
| Reporting group title | BMS-986165 (Week 0 up to Week 16) |
|-----------------------|-----------------------------------|

Reporting group description:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD).

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | Placebo (Week 0 up to Week 16) |
|-----------------------|--------------------------------|

Reporting group description:

Participants receive Placebo by oral administration once daily (QD).

|                       |                                   |
|-----------------------|-----------------------------------|
| Reporting group title | Apremilast (Week 0 up to Week 16) |
|-----------------------|-----------------------------------|

Reporting group description:

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards.

|                       |                                   |
|-----------------------|-----------------------------------|
| Reporting group title | BMS-986165 (Week 0 up to Week 52) |
|-----------------------|-----------------------------------|

Reporting group description:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD).

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | Placebo (Week 0 up to Week 52) |
|-----------------------|--------------------------------|

Reporting group description:

Participants receive Placebo by oral administration once daily (QD).

|                       |                                   |
|-----------------------|-----------------------------------|
| Reporting group title | Apremilast (Week 0 up to Week 52) |
|-----------------------|-----------------------------------|

Reporting group description:

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards.

| Serious adverse events  | BMS-986165 (Week 0 up to Week 16) | Placebo (Week 0 up to Week 16) | Apremilast (Week 0 up to Week 16) |
|---|-----------------------------------|--------------------------------|-----------------------------------|
| Total subjects affected by serious adverse events                   |                                   |                                |                                   |
| subjects affected / exposed   | 8 / 510 (1.57%)                   | 3 / 254 (1.18%)                | 1 / 254 (0.39%)                   |
| number of deaths (all causes)                                       | 1                                 | 0                              | 1                                 |
| number of deaths resulting from adverse events                      |                                   |                                |                                   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                   |                                |                                   |
| Hepatocellular carcinoma  |                                   |                                |                                   |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Lung adenocarcinoma                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 1           |
| Vascular disorders                              |                 |                 |                 |
| Malignant hypertension                          |                 |                 |                 |
| subjects affected / exposed                     | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 0 / 254 (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           |
| Peripheral artery occlusion                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 1 / 254 (0.39%) | 0 / 254 (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           |
| Shock   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Thrombosis                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Immune system disorders                         |                 |                 |                 |
| Anaphylactic reaction                           |                 |                 |                 |
| subjects affected / exposed                     | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 0 / 254 (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           |
| Reproductive system and breast disorders        |                 |                 |                 |
| Ovarian cyst                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Respiratory, thoracic and mediastinal disorders |                 |                 |                 |
| Acute respiratory failure                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Chronic obstructive pulmonary disease           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 1 / 254 (0.39%) | 0 / 254 (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           |
| Nasal septum deviation                          |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Respiratory failure                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Psychiatric disorders                           |                 |                 |                 |
| Major depression                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 1 / 254 (0.39%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Injury, poisoning and procedural complications  |                 |                 |                 |
| Post procedural haemorrhage                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Congenital, familial and genetic disorders      |                 |                 |                 |
| Gastrointestinal arteriovenous malformation     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cardiac disorders                               |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Arteriosclerosis coronary artery<br>subjects affected / exposed | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to<br>treatment / all              | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                   | 0 / 0           | 0 / 0           | 0 / 0           |
| Atrial fibrillation<br>subjects affected / exposed              | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to<br>treatment / all              | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                   | 0 / 0           | 0 / 0           | 0 / 0           |
| Cardiac arrest<br>subjects affected / exposed                   | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to<br>treatment / all              | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                   | 0 / 0           | 0 / 0           | 0 / 0           |
| Cardiac failure<br>subjects affected / exposed                  | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to<br>treatment / all              | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                   | 0 / 1           | 0 / 0           | 0 / 0           |
| Myocardial ischaemia<br>subjects affected / exposed             | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to<br>treatment / all              | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                   | 0 / 0           | 0 / 0           | 0 / 0           |
| Pericardial effusion<br>subjects affected / exposed             | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to<br>treatment / all              | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                   | 0 / 0           | 0 / 0           | 0 / 0           |
| Nervous system disorders  |                 |                 |                 |
| Cerebrovascular accident<br>subjects affected / exposed         | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to<br>treatment / all              | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                   | 0 / 0           | 0 / 0           | 0 / 0           |
| Ischaemic stroke<br>subjects affected / exposed                 | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to<br>treatment / all              | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to<br>treatment / all                   | 0 / 0           | 0 / 0           | 0 / 0           |
| Eye disorders   |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Retinal detachment                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| 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                      |                 |                 |                 |
| Anal polyp                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastrointestinal haemorrhage                    |                 |                 |                 |
| subjects affected / exposed                     | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pancreatic mass                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hepatobiliary disorders                         |                 |                 |                 |
| Hepatitis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| 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          |                 |                 |                 |
| Excessive granulation tissue                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Renal and urinary disorders                     |                 |                 |                 |
| Acute kidney injury                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| 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                     |                 |                 |                 |
| Anal abscess                                    |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| COVID-19  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cellulitis                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 1 / 254 (0.39%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Diverticulitis                                  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 0 / 254 (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           |
| Mycoplasma infection                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Purulence                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Sepsis  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 0 / 254 (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           |
| Streptococcal bacteraemia                       |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Upper respiratory tract infection               |                 |                 |                 |
| subjects affected / exposed                     | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 0 / 254 (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           |
| Vascular graft infection                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Metabolism and nutrition disorders              |                 |                 |                 |
| Dehydration                                     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 510 (0.20%) | 0 / 254 (0.00%) | 0 / 254 (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           |
| Diabetes mellitus                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 510 (0.00%) | 0 / 254 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

| <b>Serious adverse events</b>                                       | BMS-986165 (Week 0 up to Week 52) | Placebo (Week 0 up to Week 52) | Apremilast (Week 0 up to Week 52) |
|---|-----------------------------------|--------------------------------|-----------------------------------|
| Total subjects affected by serious adverse events                   |                                   |                                |                                   |
| subjects affected / exposed   | 24 / 833 (2.88%)                  | 5 / 501 (1.00%)                | 3 / 254 (1.18%)                   |
| number of deaths (all causes)                                       | 2                                 | 0                              | 1                                 |
| number of deaths resulting from adverse events                      |                                   |                                |                                   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                   |                                |                                   |
| Hepatocellular carcinoma  |                                   |                                |                                   |
| subjects affected / exposed   | 1 / 833 (0.12%)                   | 0 / 501 (0.00%)                | 0 / 254 (0.00%)                   |
| occurrences causally related to treatment / all                     | 0 / 1                             | 0 / 0                          | 0 / 0                             |
| deaths causally related to treatment / all                          | 0 / 1                             | 0 / 0                          | 0 / 0                             |
| Lung adenocarcinoma   |                                   |                                |                                   |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 833 (0.00%) | 0 / 501 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 1           |
| Vascular disorders                              |                 |                 |                 |
| Malignant hypertension                          |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Peripheral artery occlusion                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 1 / 501 (0.20%) | 0 / 254 (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           |
| Shock   |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Thrombosis                                      |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Immune system disorders                         |                 |                 |                 |
| Anaphylactic reaction                           |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Reproductive system and breast disorders        |                 |                 |                 |
| Ovarian cyst                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 0 / 501 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Respiratory, thoracic and mediastinal disorders |                 |                 |                 |
| Acute respiratory failure                       |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 833 (0.00%) | 1 / 501 (0.20%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Chronic obstructive pulmonary disease           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 1 / 501 (0.20%) | 0 / 254 (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           |
| Nasal septum deviation                          |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Respiratory failure                             |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Psychiatric disorders                           |                 |                 |                 |
| Major depression                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 1 / 501 (0.20%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Injury, poisoning and procedural complications  |                 |                 |                 |
| Post procedural haemorrhage                     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Congenital, familial and genetic disorders      |                 |                 |                 |
| Gastrointestinal arteriovenous malformation     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 0 / 501 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cardiac disorders                               |                 |                 |                 |
| Arteriosclerosis coronary artery                |                 |                 |                 |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Atrial fibrillation                             |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cardiac arrest                                  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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 failure                                 |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 1           | 0 / 0           | 0 / 0           |
| Myocardial ischaemia                            |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Pericardial effusion                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 1 / 501 (0.20%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Nervous system disorders                        |                 |                 |                 |
| Cerebrovascular accident                        |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Ischaemic stroke                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 0 / 501 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Eye disorders                                   |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Retinal detachment                              |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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                      |                 |                 |                 |
| Anal polyp                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 1 / 501 (0.20%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastrointestinal haemorrhage                    |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pancreatic mass                                 |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Hepatobiliary disorders                         |                 |                 |                 |
| Hepatitis                                       |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Excessive granulation tissue                    |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Renal and urinary disorders                     |                 |                 |                 |
| Acute kidney injury                             |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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                     |                 |                 |                 |
| Anal abscess                                    |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| COVID-19  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Cellulitis                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 1 / 501 (0.20%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Diverticulitis                                  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Mycoplasma infection                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 833 (0.00%) | 0 / 501 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia                                       |                 |                 |                 |
| subjects affected / exposed                     | 3 / 833 (0.36%) | 0 / 501 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Purulence                                       |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Sepsis  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Streptococcal bacteraemia                       |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Upper respiratory tract infection               |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Vascular graft infection                        |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Metabolism and nutrition disorders              |                 |                 |                 |
| Dehydration                                     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |
| Diabetes mellitus                               |                 |                 |                 |
| subjects affected / exposed                     | 1 / 833 (0.12%) | 0 / 501 (0.00%) | 0 / 254 (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           |

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

| <b>Non-serious adverse events</b>                     | BMS-986165 (Week 0 up to Week 16) | Placebo (Week 0 up to Week 16) | Apremilast (Week 0 up to Week 16) |
|---|-----------------------------------|--------------------------------|-----------------------------------|
| Total subjects affected by non-serious adverse events |                                   |                                |                                   |
| subjects affected / exposed                           | 114 / 510 (22.35%)                | 61 / 254 (24.02%)              | 86 / 254 (33.86%)                 |
| Nervous system disorders                              |                                   |                                |                                   |
| Headache  |                                   |                                |                                   |
| subjects affected / exposed                           | 22 / 510 (4.31%)                  | 14 / 254 (5.51%)               | 28 / 254 (11.02%)                 |
| occurrences (all)                                     | 27                                | 17                             | 31                                |
| Gastrointestinal disorders                            |                                   |                                |                                   |
| Diarrhoea   |                                   |                                |                                   |
| subjects affected / exposed                           | 24 / 510 (4.71%)                  | 19 / 254 (7.48%)               | 33 / 254 (12.99%)                 |
| occurrences (all)                                     | 26                                | 20                             | 36                                |
| Nausea  |                                   |                                |                                   |

|  |                         |                         |                        |
|--|-------------------------|-------------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)   | 7 / 510 (1.37%)<br>7    | 3 / 254 (1.18%)<br>3    | 23 / 254 (9.06%)<br>23 |
| Infections and infestations<br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all) | 55 / 510 (10.78%)<br>66 | 29 / 254 (11.42%)<br>33 | 23 / 254 (9.06%)<br>24 |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)              | 25 / 510 (4.90%)<br>28  | 11 / 254 (4.33%)<br>12  | 14 / 254 (5.51%)<br>14 |

| <b>Non-serious adverse events</b>  | BMS-986165 (Week 0 up to Week 52) | Placebo (Week 0 up to Week 52) | Apremilast (Week 0 up to Week 52) |
|--|-----------------------------------|--------------------------------|-----------------------------------|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed               | 249 / 833 (29.89%)                | 97 / 501 (19.36%)              | 98 / 254 (38.58%)                 |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)           | 45 / 833 (5.40%)<br>53            | 16 / 501 (3.19%)<br>19         | 30 / 254 (11.81%)<br>38           |
| Gastrointestinal disorders<br>Diarrhoea<br>subjects affected / exposed<br>occurrences (all)        | 39 / 833 (4.68%)<br>50            | 22 / 501 (4.39%)<br>23         | 35 / 254 (13.78%)<br>38           |
| Nausea<br>subjects affected / exposed<br>occurrences (all)   | 13 / 833 (1.56%)<br>13            | 6 / 501 (1.20%)<br>6           | 26 / 254 (10.24%)<br>27           |
| Infections and infestations<br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all) | 133 / 833 (15.97%)<br>172         | 47 / 501 (9.38%)<br>55         | 28 / 254 (11.02%)<br>33           |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)              | 74 / 833 (8.88%)<br>89            | 27 / 501 (5.39%)<br>31         | 21 / 254 (8.27%)<br>23            |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date        | Amendment   |
|-------------|---|
| 14 May 2019 | 1) Randomization in each country will be targeted to approximately 35% or less of the total sample size.<br>2) Added the 'Time to relapse until Week 52' endpoint |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported