



Clinical trial results:

A Phase IIB Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy with BMS-936557 in Subjects with Active Ulcerative Colitis

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2010-022506-41 |
| Trial protocol | DE AT HU BE PL IT |
| Global end of trial date | 05 January 2015 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 (current) |
| This version publication date | 31 August 2016 |
| First version publication date | 31 August 2016 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | IM129-005 |
|-----------------------|-----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01294410 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Bristol-Myers Squibb |
| Sponsor organisation address | Bristol-Myers Squibb International Corporation, Chaussée de la Hulpe 185, Brussels, Belgium, 1170 |
| Public contact | Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, 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 | 05 January 2015 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|-----------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 05 January 2015 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to compare the efficacy of BMS-936557 vs placebo for induction of clinical remission (defined as Mayo score ≤ 2 points with no individual subscore >1 point) at Week 11.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 27 March 2011 |
| 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: 33 |
| Country: Number of subjects enrolled | Brazil: 22 |
| Country: Number of subjects enrolled | Canada: 21 |
| Country: Number of subjects enrolled | Mexico: 37 |
| Country: Number of subjects enrolled | South Africa: 10 |
| Country: Number of subjects enrolled | United States: 114 |
| Country: Number of subjects enrolled | Netherlands: 10 |
| Country: Number of subjects enrolled | Poland: 50 |
| Country: Number of subjects enrolled | Austria: 12 |
| Country: Number of subjects enrolled | Belgium: 4 |
| Country: Number of subjects enrolled | France: 42 |
| Country: Number of subjects enrolled | Germany: 11 |
| Country: Number of subjects enrolled | Hungary: 31 |
| Country: Number of subjects enrolled | Italy: 14 |
| Worldwide total number of subjects | 411 |
| EEA total number of subjects | 174 |

Notes:

| Subjects enrolled per age group | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 384 |
| From 65 to 84 years | 27 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

A total of 411 subjects were enrolled at 75 sites in 14 countries.

Pre-assignment

Screening details:

A total of 411 subjects were enrolled, 305 subjects were randomised and treated in the induction period. Reasons for 106 subjects not randomised were: Adverse event-1; Subject withdrew consent-15; Lost to follow up-5; Poor/Non-compliance-2; Study criteria not met-74; Administrative reason by sponsor-1; other-8.

Period 1

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

Arms

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

Arm description:

Subjects received BMS-936557 matching placebo, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

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

Dosage and administration details:

Subjects received placebo matching with BMS 936557 via intravenous infusion over 90 minutes once a week for first two weeks and every other week thereafter, up to 11 weeks.

| | |
|------------------|---------------------|
| Arm title | BMS-936557 15 mg/kg |
|------------------|---------------------|

Arm description:

Subjects received BMS-936557 15 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

| | |
|--|-----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-936557 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects received BMS-936557 15 mg/kg via intravenous infusion over 90 minutes, once a week for first two weeks and every other week thereafter, up to 11 weeks.

| | |
|------------------|---------------------|
| Arm title | BMS-936557 25 mg/kg |
|------------------|---------------------|

Arm description:

Subjects received BMS-936557 25 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|-----------------------|
| Investigational medicinal product name | BMS-936557 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects received BMS-936557 25 mg/kg via intravenous infusion over 90 minutes, once a week for first two weeks and every other week thereafter, up to 11 weeks.

| Number of subjects in period 1^[1] | Placebo | BMS-936557 15 mg/kg | BMS-936557 25 mg/kg |
|---|---------|---------------------|---------------------|
| Started | 100 | 102 | 103 |
| Completed | 85 | 90 | 90 |
| Not completed | 15 | 12 | 13 |
| Consent withdrawn by subject | 3 | 1 | 3 |
| Adverse event, non-fatal | 1 | 5 | 5 |
| Subject request to discontinue study treatment | 3 | 2 | 1 |
| Other reasons | 1 | - | - |
| Lost to follow-up | - | 1 | 1 |
| Subject no longer meets study criteria | - | - | 1 |
| Lack of efficacy | 7 | 3 | 2 |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial as out of total 411 subjects who were enrolled, 305 subjects were randomised and treated in the induction period. Reasons for 106 subjects not randomised were: Adverse event-1; Subject withdrew consent-15; Lost to follow up-5; Poor/Non-compliance-2; Study criteria not met-74; Administrative reason by sponsor-1; other-8.

Period 2

| | |
|------------------------------|--|
| Period 2 title | Maintenance Period |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

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

Arm description:

Subjects who received placebo in the induction period received placebo intravenous infusion over 90 minutes, every other week for up to 108 weeks.

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

| | |
|---|-----------------------|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Subjects received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Arm title | BMS-936557 to Placebo |
| Arm description: | |
| Subjects who received any dose of BMS-936557 in the induction period received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Arm type | Experimental |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Subjects received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Arm title | BMS-936557 5 mg/kg |
| Arm description: | |
| Subjects received BMS-936557 5 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Arm type | Experimental |
| Investigational medicinal product name | BMS-936557 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Subjects received BMS-936557 5 mg/kg via intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Arm title | BMS-936557 10 mg/kg |
| Arm description: | |
| Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Arm type | Experimental |
| Investigational medicinal product name | BMS-936557 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Subjects received BMS-936557 10 mg/kg via intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Arm title | BMS-936557 20 mg/kg |
| Arm description: | |
| Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Arm type | Experimental |

| | |
|--|-----------------------|
| Investigational medicinal product name | BMS-936557 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects received BMS-936557 20 mg/kg via intravenous infusion over 90 minutes, every other week for up to 108 weeks.

| Number of subjects in period 2^[2] | Placebo to Placebo | BMS-936557 to Placebo | BMS-936557 5 mg/kg |
|---|--------------------|-----------------------|--------------------|
| Started | 30 | 22 | 24 |
| Completed | 7 | 4 | 5 |
| Not completed | 23 | 18 | 19 |
| Consent withdrawn by subject | 1 | 1 | - |
| Adverse event, non-fatal | - | - | - |
| Subject request to discontinue study treatment | 2 | 1 | 2 |
| Pregnancy | - | 1 | - |
| Other reasons | - | 1 | - |
| Lost to follow-up | - | - | 1 |
| Lack of efficacy | 20 | 14 | 16 |

| Number of subjects in period 2^[2] | BMS-936557 10 mg/kg | BMS-936557 20 mg/kg |
|---|---------------------|---------------------|
| Started | 22 | 21 |
| Completed | 5 | 5 |
| Not completed | 17 | 16 |
| Consent withdrawn by subject | - | 1 |
| Adverse event, non-fatal | 2 | 2 |
| Subject request to discontinue study treatment | 2 | 1 |
| Pregnancy | - | - |
| Other reasons | - | - |
| Lost to follow-up | - | - |
| Lack of efficacy | 13 | 12 |

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Out of 265 subjects who completed the induction period, only 119 subjects entered the maintenance period. 142 subjects discontinued and moved directly into the open label period.

Period 3

| | |
|------------------------------|-------------------|
| Period 3 title | Open-Label Period |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------|---------------------|
| Arm title | BMS-936557 10 mg/kg |
|------------------|---------------------|

Arm description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 41 months.

| | |
|--|-----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-936557 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects were administered BMS-936557 ~10 mg/kg via intravenous infusion over 90 minutes, every other week for up to 41 months.

| Number of subjects in period 3^[3] | BMS-936557 10 mg/kg |
|---|---------------------|
| Started | 23 |
| Completed | 0 |
| Not completed | 237 |
| Consent withdrawn by subject | 20 |
| Adverse event, non-fatal | 15 |
| Subject request to discontinue study treatment | 16 |
| Death | 1 |
| Poor/Non-compliance | 1 |
| Other reasons | 7 |
| Lost to follow-up | 2 |
| Subject no longer meets study criteria | 1 |
| Lack of efficacy | 95 |
| Administrative reason by sponsor | 79 |
| Joined | 214 |
| Continued from IP and MP | 214 |

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Among the 119 subjects treated in the maintenance phase, 26 subjects completed and entered the open label period. 142 subjects moved directly into open label period from the induction

period. A total of 238 subjects entered the open label period of whom 237 subjects were treated and 1 subject from the induction period was not treated. 214 subjects continued from IP and MP.

Baseline characteristics

Reporting groups

| | |
|---|---------------------|
| Reporting group title | Placebo |
| Reporting group description: Subjects received BMS-936557 matching placebo, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks. | |
| Reporting group title | BMS-936557 15 mg/kg |
| Reporting group description: Subjects received BMS-936557 15 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks. | |
| Reporting group title | BMS-936557 25 mg/kg |
| Reporting group description: Subjects received BMS-936557 25 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks. | |

| Reporting group values | Placebo | BMS-936557 15 mg/kg | BMS-936557 25 mg/kg |
|---------------------------------------|---------|---------------------|---------------------|
| Number of subjects | 100 | 102 | 103 |
| Age categorical Units: Subjects | | | |
| 18 - <40 years | 42 | 54 | 55 |
| 40 - <65 years | 51 | 42 | 42 |
| >=65 - <75 years | 7 | 5 | 5 |
| >=75 years | 0 | 1 | 1 |
| Gender categorical Units: Subjects | | | |
| Female | 47 | 36 | 47 |
| Male | 53 | 66 | 56 |

| Reporting group values | Total | | |
|---------------------------------------|-------|--|--|
| Number of subjects | 305 | | |
| Age categorical Units: Subjects | | | |
| 18 - <40 years | 151 | | |
| 40 - <65 years | 135 | | |
| >=65 - <75 years | 17 | | |
| >=75 years | 2 | | |
| Gender categorical Units: Subjects | | | |
| Female | 130 | | |
| Male | 175 | | |

Subject analysis sets

| | |
|---|--------------------|
| Subject analysis set title | IP - Placebo |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects received BMS-936557 matching placebo, intravenously, once weekly for the first two weeks and every other week thereafter up to 11 weeks (Post-amendment 4). | |

| | |
|---|-------------------------|
| Subject analysis set title | IP- BMS-936557 15 mg/kg |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: | |
| Subjects received BMS 936557 15 mg/kg intravenous infusion, once a week for the first two weeks and every other week thereafter, up to 11 weeks (Post-amendment 4). | |
| Subject analysis set title | IP BMS-936557 25 mg/kg |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: | |
| Subjects received BMS 936557 25 mg/kg intravenous infusion, once a week for the first two weeks and every other week thereafter, up to 11 weeks (Post-amendment 4). | |

| Reporting group values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg |
|------------------------|--------------|-------------------------|------------------------|
| Number of subjects | 83 | 84 | 85 |
| Age categorical | | | |
| Units: Subjects | | | |
| 18 - <40 years | 38 | 45 | 48 |
| 40 - <65 years | 39 | 33 | 34 |
| >=65 - <75 years | 6 | 5 | 2 |
| >=75 years | 0 | 1 | 1 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 40 | 30 | 41 |
| Male | 43 | 54 | 44 |

End points

End points reporting groups

| | |
|---|-------------------------|
| Reporting group title | Placebo |
| Reporting group description: Subjects received BMS-936557 matching placebo, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks. | |
| Reporting group title | BMS-936557 15 mg/kg |
| Reporting group description: Subjects received BMS-936557 15 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks. | |
| Reporting group title | BMS-936557 25 mg/kg |
| Reporting group description: Subjects received BMS-936557 25 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks. | |
| Reporting group title | Placebo to Placebo |
| Reporting group description: Subjects who received placebo in the induction period received placebo intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Reporting group title | BMS-936557 to Placebo |
| Reporting group description: Subjects who received any dose of BMS-936557 in the induction period received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Reporting group title | BMS-936557 5 mg/kg |
| Reporting group description: Subjects received BMS-936557 5 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Reporting group title | BMS-936557 10 mg/kg |
| Reporting group description: Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Reporting group title | BMS-936557 20 mg/kg |
| Reporting group description: Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks. | |
| Reporting group title | BMS-936557 10 mg/kg |
| Reporting group description: Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 41 months. | |
| Subject analysis set title | IP - Placebo |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects received BMS-936557 matching placebo, intravenously, once weekly for the first two weeks and every other week thereafter up to 11 weeks (Post-amendment 4). | |
| Subject analysis set title | IP- BMS-936557 15 mg/kg |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects received BMS 936557 15 mg/kg intravenous infusion, once a week for the first two weeks and every other week thereafter, up to 11 weeks (Post-amendment 4). | |
| Subject analysis set title | IP BMS-936557 25 mg/kg |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects received BMS 936557 25 mg/kg intravenous infusion, once a week for the first two weeks and every other week thereafter, up to 11 weeks (Post-amendment 4). | |

Primary: Percentage of Subjects Who Achieved Clinical Remission at Week 11 (Induction period)

| | |
|-----------------|--|
| End point title | Percentage of Subjects Who Achieved Clinical Remission at Week 11 (Induction period) |
|-----------------|--|

End point description:

Clinical remission was defined as a total Mayo score of at least 2 and no individual sub-score greater than 1. The Mayo scoring system is a composite index consisting of 4 disease variables (each scored on a scale of 0 to 3, with higher scores indicating greater frequency or severity): stool frequency, rectal bleeding, findings on endoscopy, and the physician's global assessment. Mayo scores range from 0 to 12 points and utilize all 4 disease variables, with higher scores indicating more severe disease. The analysis was performed in all treated subjects who received any study drug.

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

End point timeframe:

Start of induction period (Day 1) up to Week 11

| End point values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg | |
|----------------------------------|----------------------|-------------------------|------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 83 | 84 | 85 | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 9.6 (3.3 to 16) | 13.1 (5.9 to 20.3) | 17.6 (9.5 to 25.8) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | BMS-936557 15mg/kg vs Placebo |
| Comparison groups | IP- BMS-936557 15 mg/kg v IP - Placebo |
| Number of subjects included in analysis | 167 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.515 |
| Method | Cochran-Mantel-Haenszel Chi-square test |
| Parameter estimate | Absolute treatment difference |
| Point estimate | 3.1 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -8.3 |
| upper limit | 14.5 |

| | |
|-----------------------------------|---------------------------------------|
| Statistical analysis title | BMS-936557 25mg/kg vs Placebo |
| Comparison groups | IP - Placebo v IP BMS-936557 25 mg/kg |

| | |
|---|---|
| Number of subjects included in analysis | 168 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.158 |
| Method | Cochran-Mantel-Haenszel Chi-square test |
| Parameter estimate | Absolute treatment difference |
| Point estimate | 7.6 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -3.9 |
| upper limit | 19.2 |

Secondary: Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Total and Subscale Scores (Bowel, Systemic, Social, and emotional Symptoms) at Week 11

| | |
|-----------------|---|
| End point title | Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Total and Subscale Scores (Bowel, Systemic, Social, and emotional Symptoms) at Week 11 |
|-----------------|---|

End point description:

IBDQ was used to measure disease specific quality of life (QoL). The IBDQ consists of a self-administered 32-item questionnaire that evaluates QoL across 4 dimensional scores: Bowel, Systemic, Social and Emotional. The response to each question can range from 1 to 7, with 1 indicating severe problem and 7 indicating normal health. The total IBDQ is computed as the sum of the responses to the individual IBDQ questions. The total score can range between 32 to 224 with higher scores indicating a better QoL. The analysis was performed in all treated subjects who received the study drug. Here "n" refers to the number of treated subjects with non-missing baseline and post-baseline values.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 11 | |

| End point values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg | |
|--------------------------------------|----------------------|-------------------------|------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 83 | 84 | 85 | |
| Units: Score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Bowel symptoms (n=78, 75, 74) | 4.18 (± 13.551) | 8.41 (± 10.205) | 11.16 (± 13.673) | |
| Systemic symptoms (n=78, 75, 74) | 2.08 (± 6.326) | 3.95 (± 5.46) | 4.3 (± 6.957) | |
| Emotional symptoms (n=78, 75, 74) | 4.98 (± 14.601) | 7.75 (± 11.722) | 9.65 (± 16.686) | |
| Social symptoms (n=78, 75, 74) | 1.93 (± 7.903) | 3.92 (± 6.594) | 3.82 (± 8.744) | |
| Total Score (n=78, 75, 74) | 13.17 (± 38.955) | 24.03 (± 30.082) | 28.93 (± 43.136) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Inflammatory Bowel Disease Questionnaire (IBDQ) Response at Week 11 (IP-78)

| | |
|--|---|
| End point title | Percentage of Subjects With Inflammatory Bowel Disease Questionnaire (IBDQ) Response at Week 11 (IP-78) |
| End point description: IBDQ response was defined as change from baseline in IBDQ score of ≥ 16 points. The analysis was performed in all treated subjects who received the study drug. | |
| End point type | Secondary |
| End point timeframe: Week 11 | |

| End point values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg | |
|----------------------------------|----------------------|-------------------------|------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 83 | 84 | 85 | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 38.6 (28.1 to 49) | 45.2 (34.6 to 55.9) | 51.8 (41.1 to 62.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Clinical Response at Week 11

| | |
|--|--|
| End point title | Percentage of Subjects Who Achieved Clinical Response at Week 11 |
| End point description: Clinical response was defined as reduction from baseline in Mayo score of at least 3 points and at least 30%, with an accompanying decrease in the subscore for rectal bleeding of at least 1 point or an absolute subscore for rectal bleeding of 0 or 1. The Mayo scoring system is a composite index consisting of 4 disease variables (each scored on a scale of 0 to 3, with higher scores indicating greater frequency or severity): stool frequency, rectal bleeding, findings on endoscopy, and the physician's global assessment. Mayo scores range from 0 to 12 points and utilize all 4 disease variables, with higher scores indicating more severe disease. The analysis was performed in all treated subjects who received any study drug. | |
| End point type | Secondary |
| End point timeframe: Start of induction period (Day 1) up to Week 11 | |

| End point values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg | |
|----------------------------------|----------------------|-------------------------|------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 83 | 84 | 85 | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 31.3 (21.3 to 41.3) | 44 (33.4 to 54.7) | 47.1 (36.4 to 57.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Mucosal Healing at Week 11

| | |
|-----------------|--|
| End point title | Percentage of Subjects Who Achieved Mucosal Healing at Week 11 |
|-----------------|--|

End point description:

Mucosal healing was defined as endoscopic subscore ≤ 1 point. Endoscopy was performed using Sigmoidoscopy. Findings of flexible proctosigmoidoscopy were rated as: 0 = Normal or inactive disease, 1 = Mild disease (erythema, decreased vascular pattern, mild friability), 2 = Moderate disease (marked erythema, absent vascular pattern, friability, erosions), and 3 = Severe disease (spontaneous bleeding, ulceration). The analysis was performed in all the subjects who were randomised and received any study drug.

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

End point timeframe:

Start of induction period (Day 1) up to Week 11

| End point values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg | |
|----------------------------------|----------------------|-------------------------|------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 83 | 84 | 85 | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 27.7 (18.1 to 37.3) | 29.8 (20 to 39.5) | 31.8 (21.9 to 41.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Adverse Events (AEs), Drug related AEs, Discontinuation due to AEs, Serious Adverse Events (SAEs), Drug related SAEs, Discontinuation Due to SAEs, and Who Died

| | |
|--|---|
| End point title | Number of Subjects With Adverse Events (AEs), Drug related AEs, Discontinuation due to AEs, Serious Adverse Events (SAEs), Drug related SAEs, Discontinuation Due to SAEs, and Who Died |
| End point description: An AE is any new unfavorable symptom, sign, or disease or worsening of a preexisting condition that may not have a causal relationship with treatment. An SAE is a medical event that at any dose results in death, persistent or significant disability/incapacity, or drug dependency/abuse; is life-threatening, an important medical event, or a congenital anomaly/birth defect; or requires or prolongs hospitalization. The analysis was performed in all the subjects who received any study medication. | |
| End point type | Secondary |
| End point timeframe: Baseline (Day 1) up to 56 days after the last dose in the induction period/start of the subsequent phase treatment, which ever occurred first. | |

| End point values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg | |
|-----------------------------|----------------------|-------------------------|------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 83 | 84 | 85 | |
| Units: Subjects | | | | |
| AEs | 57 | 56 | 60 | |
| Drug related AEs | 16 | 27 | 33 | |
| Discontinuation due to AEs | 4 | 5 | 4 | |
| SAEs | 8 | 4 | 4 | |
| Drug related SAEs | 0 | 1 | 2 | |
| Discontinuation Due to SAEs | 4 | 2 | 2 | |
| Death | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Marked Hematology Laboratory Abnormalities During Induction period

| | |
|---|--|
| End point title | Number of Subjects With Marked Hematology Laboratory Abnormalities During Induction period |
| End point description: Erythrocytes, Low: if value $<0.75 \times \text{baseline value (PRE)}$ and $< \text{lower limit of normal (LLN)}$; Hematocrit, Low: if value $<0.75 \times \text{PRE}$ and $< \text{LLN}$; Hemoglobin, Low: $< \text{PRE} - 30$ and $< \text{LLN}$; Platelet Count, Low: if $\text{LLN} \leq \text{PRE} \leq \text{upper limit of normal (ULN)}$ and value $<0.67 \times \text{LLN}$, or if $\text{PRE} < \text{LLN}$ and value $<0.5 \times \text{PRE}$ and value <100 ; Platelet Count, High: if $\text{LLN} \leq \text{PRE} \leq \text{ULN}$ and value $>1.5 \times \text{ULN}$; Total White Blood Cells (WBC) count, Low: if $\text{LLN} \leq \text{PRE} \leq \text{limit of normal (ULN)}$ and value $<0.75 \times \text{LLN}$, or if $\text{PRE} < \text{LLN}$ and Value $<0.8 \times \text{PRE}$, or if $\text{PRE} > \text{ULN}$ and value $< \text{LLN}$; Total WBC Count, High: if $\text{LLN} \leq \text{PRE} \leq \text{ULN}$ and value $>1.25 \times \text{ULN}$, or if $\text{PRE} < \text{LLN}$ and value $> \text{ULN}$, or if $\text{PRE} > \text{ULN}$ and value $>1.2 \times \text{PRE}$. Lymphocytes, Low (absolute): if value <0.75 and $< \text{LLN}$; Lymphocytes, High (absolute): if value >7.5 and $> \text{ULN}$; Neutrophils, Low (absolute): if value <1.0 and $< \text{LLN}$. The analysis was performed in all the subjects who received any study drug. Here, 'n' signifies evaluable subjects for specified categories in respective treatment arms. | |
| End point type | Secondary |
| End point timeframe: Baseline (Day 1) up to 56 days after the last dose in the induction period/start of the subsequent phase treatment, which ever occurred first. | |

| End point values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg | |
|---|----------------------|-------------------------|------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 83 | 84 | 85 | |
| Units: Subjects | | | | |
| Erythrocytes, Low (n=83, 82, 84) | 1 | 1 | 0 | |
| Hematocrit, Low (n=83, 82, 84) | 2 | 0 | 1 | |
| Hemoglobin, Low (n=83, 82, 84) | 3 | 0 | 1 | |
| Platelet Count, Low (n=83, 82, 84) | 0 | 0 | 0 | |
| Platelet Count, High (n=83, 82, 84) | 2 | 0 | 1 | |
| Total WBC count, Low (n=83, 82, 84) | 1 | 0 | 1 | |
| Total WBC count, High (n=83, 82, 84) | 3 | 6 | 2 | |
| Lymphocytes, Low (absolute) (n=83, 82, 84) | 17 | 15 | 19 | |
| Lymphocytes, High (absolute) (n=83, 82, 84) | 1 | 0 | 0 | |
| Neutrophils, Low (absolute) (n=83, 82, 84) | 0 | 0 | 1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Marked Liver and Kidney Function Laboratory Abnormalities During Induction Period

| | |
|-----------------|---|
| End point title | Number of Subjects With Marked Liver and Kidney Function Laboratory Abnormalities During Induction Period |
|-----------------|---|

End point description:

Alanine Aminotransferase (ALT), High: if lower limit of normal (LLN) \leq baseline value (PRE) \leq upper limit of normal (ULN) and value $>3 \times$ ULN, or if PRE $>$ ULN and value $>4 \times$ PRE; Alkaline Phosphatase (ALP), High: if LLN \leq PRE \leq ULN and value $>2 \times$ ULN, or if PRE $>$ ULN and value $>3 \times$ PRE; Aspartate Aminotransferase (AST), High: if LLN \leq PRE \leq ULN and value $>3 \times$ ULN, or if PRE $>$ ULN and value $>4 \times$ PRE; Bilirubin, Total, High: if LLN \leq PRE \leq ULN and value $>2 \times$ ULN, or if PRE $>$ ULN and value $>4 \times$ PRE; G-Glutamyl Transferase (GGT), High: if LLN \leq PRE \leq ULN and value $>2 \times$ ULN, or if PRE $>$ ULN and value $>3 \times$ PRE; Creatinine, High: if value $>1.5 \times$ PRE and $>$ ULN. The analysis was performed in all the subjects who received any study drug. Here, 'n' signifies evaluable subjects for specified categories in respective treatment arms.

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

End point timeframe:

Baseline (Day 1) up to 56 days after the last dose in the induction period/start of the subsequent phase treatment, whichever occurred first.

| End point values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg | |
|--------------------------------------|----------------------|-------------------------|------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 83 | 84 | 85 | |
| Units: Subjects | | | | |
| ALT, High (n=83, 82, 84) | 0 | 0 | 1 | |
| ALP, High (n=83, 82, 84) | 0 | 0 | 0 | |
| AST, High (n=83, 82, 84) | 0 | 1 | 1 | |
| Total Bilirubin, High (n=83, 82, 84) | 0 | 0 | 0 | |
| GGT, High (n=83, 82, 84) | 2 | 1 | 1 | |
| Creatinine, High (n=83, 82, 84) | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Marked Chemistry Laboratory Abnormalities During Induction period

| | |
|-----------------|---|
| End point title | Number of Subjects With Marked Chemistry Laboratory Abnormalities During Induction period |
|-----------------|---|

End point description:

Glucose (fasting serum), Low: if lower limit of normal (LLN) \leq baseline value (PRE) \leq upper limit of normal (ULN) and value $< 0.8 \times \text{LLN}$, or if PRE $< \text{LLN}$ and value $< 0.8 \times \text{PRE}$, or if PRE $> \text{ULN}$ and value $< \text{LLN}$; Glucose (fasting serum), High: if LLN $\leq \text{PRE} \leq \text{ULN}$ and value $> 1.5 \times \text{ULN}$, or if PRE $< \text{LLN}$ and value $> \text{ULN}$, or if PRE $> \text{ULN}$ and value $> 2.0 \times \text{PRE}$; Albumin, Low: if LLN $\leq \text{PRE} \leq \text{ULN}$ and value $< 0.9 \times \text{LLN}$, or if PRE $< \text{LLN}$ and value $< 0.75 \times \text{PRE}$. The analysis was performed in all the subjects who received any study drug. Here, 'n' signifies evaluable subjects for specified categories in respective treatment arms.

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

End point timeframe:

Baseline (Day 1) up to 56 days after the last dose in the induction period/start of the subsequent phase treatment, whichever occurred first.

| End point values | IP - Placebo | IP- BMS-936557 15 mg/kg | IP BMS-936557 25 mg/kg | |
|---|----------------------|-------------------------|------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 83 | 84 | 85 | |
| Units: Subjects | | | | |
| Glucose (fasting serum) Low (n=63, 66, 62) | 1 | 2 | 0 | |
| Glucose (fasting serum) High (n=63, 66, 62) | 2 | 0 | 0 | |
| Albumin, Low (n=83, 82, 84) | 2 | 0 | 0 | |

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On-Treatment period (up to 56 days after the last dose of the study drug)

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 17.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | IP: Placebo |
|-----------------------|-------------|

Reporting group description:

Subjects received BMS-936557 matching placebo, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

| | |
|-----------------------|-------------------------|
| Reporting group title | IP: BMS-936557 15 mg/kg |
|-----------------------|-------------------------|

Reporting group description:

Subjects received BMS-936557 15 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

| | |
|-----------------------|-------------------------|
| Reporting group title | IP: BMS-936557 25 mg/kg |
|-----------------------|-------------------------|

Reporting group description:

Subjects received BMS-936557 25 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

| | |
|-----------------------|------------------------|
| Reporting group title | MP: Placebo to Placebo |
|-----------------------|------------------------|

Reporting group description:

Subjects who received placebo in the induction period received placebo intravenous infusion over 90 minutes, every other week for up to 108 weeks.

| | |
|-----------------------|---------------------------|
| Reporting group title | MP: BMS-936557 to Placebo |
|-----------------------|---------------------------|

Reporting group description:

Subjects who received any dose of BMS-936557 in the induction period received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks.

| | |
|-----------------------|------------------------|
| Reporting group title | MP: BMS-936557 5 mg/kg |
|-----------------------|------------------------|

Reporting group description:

Subjects received BMS-936557 5 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.

| | |
|-----------------------|-------------------------|
| Reporting group title | MP: BMS-936557 10 mg/kg |
|-----------------------|-------------------------|

Reporting group description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.

| | |
|-----------------------|-------------------------|
| Reporting group title | MP: BMS-936557 20 mg/kg |
|-----------------------|-------------------------|

Reporting group description:

Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.

| | |
|-----------------------|-------------------------|
| Reporting group title | OL: BMS-936557 10 mg/kg |
|-----------------------|-------------------------|

Reporting group description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 41 months.

| Serious adverse events | IP: Placebo | IP: BMS-936557 15 mg/kg | IP: BMS-936557 25 mg/kg |
|---|-----------------|-------------------------|-------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 9 / 100 (9.00%) | 6 / 102 (5.88%) | 5 / 103 (4.85%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 0 / 102 (0.00%) | 0 / 103 (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 |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 1 / 102 (0.98%) | 0 / 103 (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 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 1 / 102 (0.98%) | 0 / 103 (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 |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 1 / 103 (0.97%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 1 / 103 (0.97%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Prostatitis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| 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 | | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 1 / 102 (0.98%) | 0 / 103 (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 |
| Psychiatric disorders | | | |
| Disorientation | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Major depression | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Cytomegalovirus test positive | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 1 / 103 (0.97%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 0 / 102 (0.00%) | 0 / 103 (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 | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 0 / 102 (0.00%) | 0 / 103 (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 |
| Eye disorders | | | |
| Diplopia | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 5 / 100 (5.00%) | 5 / 102 (4.90%) | 2 / 103 (1.94%) |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 5 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon dysplasia | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diverticular perforation | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Proctitis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| 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 | | | |
| Urticaria | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| 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 | | | |
| Calculus ureteric | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 0 / 102 (0.00%) | 0 / 103 (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 failure acute | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Goitre | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| 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 Abscess limb subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 100 (0.00%) 0 / 0 0 / 0 | 0 / 102 (0.00%) 0 / 0 0 / 0 | 0 / 103 (0.00%) 0 / 0 0 / 0 |
| Anal abscess subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 100 (0.00%) 0 / 0 0 / 0 | 0 / 102 (0.00%) 0 / 0 0 / 0 | 0 / 103 (0.00%) 0 / 0 0 / 0 |
| Anal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 100 (0.00%) 0 / 0 0 / 0 | 0 / 102 (0.00%) 0 / 0 0 / 0 | 0 / 103 (0.00%) 0 / 0 0 / 0 |
| Bronchitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 100 (0.00%) 0 / 0 0 / 0 | 0 / 102 (0.00%) 0 / 0 0 / 0 | 0 / 103 (0.00%) 0 / 0 0 / 0 |
| Catheter site infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 100 (0.00%) 0 / 0 0 / 0 | 0 / 102 (0.00%) 0 / 0 0 / 0 | 0 / 103 (0.00%) 0 / 0 0 / 0 |
| Cellulitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 100 (0.00%) 0 / 0 0 / 0 | 0 / 102 (0.00%) 0 / 0 0 / 0 | 0 / 103 (0.00%) 0 / 0 0 / 0 |
| Chronic tonsillitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 100 (0.00%) 0 / 0 0 / 0 | 0 / 102 (0.00%) 0 / 0 0 / 0 | 0 / 103 (0.00%) 0 / 0 0 / 0 |
| Cytomegalovirus colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 100 (0.00%) 0 / 0 0 / 0 | 0 / 102 (0.00%) 0 / 0 0 / 0 | 0 / 103 (0.00%) 0 / 0 0 / 0 |
| Gastroenteritis salmonella | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mycotic aneurysm | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| 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 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal abscess | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal endocarditis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 0 / 102 (0.00%) | 0 / 103 (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 |
| Tonsillitis streptococcal | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 0 / 102 (0.00%) | 0 / 103 (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 | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Type 1 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | MP: Placebo to Placebo | MP: BMS-936557 to Placebo | MP: BMS-936557 5 mg/kg |
|---|------------------------|---------------------------|------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 30 (6.67%) | 1 / 22 (4.55%) | 2 / 24 (8.33%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 22 (0.00%) | 0 / 24 (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 |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Reproductive system and breast disorders | | | |
| Prostatitis | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 22 (0.00%) | 0 / 24 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |
| Disorientation | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Major depression | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Cytomegalovirus test positive | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|----------------|----------------|----------------|
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Diplopia | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon dysplasia | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diverticular perforation | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Proctitis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |
| Urticaria | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |
| Calculus ureteric | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 failure acute | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |

| | | | |
|---|----------------|----------------|----------------|
| Goitre | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 22 (4.55%) | 0 / 24 (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 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |
| Abscess limb | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal infection | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Catheter site infection | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 tonsillitis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytomegalovirus colitis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis salmonella | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mycotic aneurysm | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal abscess | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal endocarditis | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 22 (0.00%) | 0 / 24 (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 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis streptococcal | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| 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 | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Type 1 diabetes mellitus | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 22 (0.00%) | 0 / 24 (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 |

| | | | |
|-------------------------------|-------------------|-------------------|-------------------|
| Serious adverse events | MP: BMS-936557 10 | MP: BMS-936557 20 | OL: BMS-936557 10 |
|-------------------------------|-------------------|-------------------|-------------------|

| | mg/kg | mg/kg | mg/kg |
|---|-----------------|----------------|-------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | 2 / 21 (9.52%) | 45 / 237 (18.99%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 21 (0.00%) | 0 / 237 (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 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |

| | | | |
|---|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 21 (4.76%) | 0 / 237 (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 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| 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 | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Prostatitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| 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 | | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| 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 | | | |
| Disorientation | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Major depression | | | |

| | | | |
|---|----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 21 (0.00%) | 0 / 237 (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 |
| Suicidal ideation | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 21 (0.00%) | 0 / 237 (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 |
| Investigations | | | |
| Cytomegalovirus test positive | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| 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 failure | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|------------------|
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Diplopia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 21 (4.76%) | 0 / 237 (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 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 21 (0.00%) | 21 / 237 (8.86%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 22 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon dysplasia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diverticular perforation | | | |

| | | | |
|---|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 21 (4.76%) | 0 / 237 (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 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Proctitis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Urticaria | | | |

| | | | |
|---|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Calculus ureteric | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal failure acute | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Goitre | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 21 (4.76%) | 0 / 237 (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 |

| | | | |
|---|----------------------------------|----------------------------------|-----------------------------------|
| Infections and infestations Abscess limb subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 22 (0.00%) 0 / 0 0 / 0 | 0 / 21 (0.00%) 0 / 0 0 / 0 | 1 / 237 (0.42%) 0 / 1 0 / 0 |
| Anal abscess subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 22 (0.00%) 0 / 0 0 / 0 | 0 / 21 (0.00%) 0 / 0 0 / 0 | 1 / 237 (0.42%) 0 / 1 0 / 0 |
| Anal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 22 (0.00%) 0 / 0 0 / 0 | 0 / 21 (0.00%) 0 / 0 0 / 0 | 1 / 237 (0.42%) 1 / 1 0 / 0 |
| Bronchitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 22 (0.00%) 0 / 0 0 / 0 | 0 / 21 (0.00%) 0 / 0 0 / 0 | 1 / 237 (0.42%) 0 / 1 0 / 0 |
| Catheter site infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 22 (0.00%) 0 / 0 0 / 0 | 0 / 21 (0.00%) 0 / 0 0 / 0 | 1 / 237 (0.42%) 0 / 1 0 / 0 |
| Cellulitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 22 (0.00%) 0 / 0 0 / 0 | 0 / 21 (0.00%) 0 / 0 0 / 0 | 1 / 237 (0.42%) 0 / 1 0 / 0 |
| Chronic tonsillitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 22 (0.00%) 0 / 0 0 / 0 | 0 / 21 (0.00%) 0 / 0 0 / 0 | 1 / 237 (0.42%) 0 / 1 0 / 0 |
| Cytomegalovirus colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 22 (0.00%) 0 / 0 0 / 0 | 0 / 21 (0.00%) 0 / 0 0 / 0 | 1 / 237 (0.42%) 1 / 1 0 / 0 |
| Gastroenteritis salmonella | | | |

| | | | |
|---|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mycotic aneurysm | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 21 (4.76%) | 0 / 237 (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 |
| Rectal abscess | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal endocarditis | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis streptococcal | | | |

| | | | |
|---|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| 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 | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Type 1 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | IP: Placebo | IP: BMS-936557 15 mg/kg | IP: BMS-936557 25 mg/kg |
|---|-------------------|-------------------------|-------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 44 / 100 (44.00%) | 42 / 102 (41.18%) | 53 / 103 (51.46%) |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 2 / 102 (1.96%) | 3 / 103 (2.91%) |
| occurrences (all) | 1 | 2 | 7 |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 3 / 102 (2.94%) | 3 / 103 (2.91%) |
| occurrences (all) | 2 | 3 | 3 |
| Headache | | | |

| | | | |
|---|-----------------------|-------------------------|-------------------------|
| subjects affected / exposed occurrences (all) | 6 / 100 (6.00%) 10 | 12 / 102 (11.76%) 19 | 18 / 103 (17.48%) 25 |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 1 / 100 (1.00%) 1 | 4 / 102 (3.92%) 4 | 5 / 103 (4.85%) 5 |
| General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all) | 6 / 100 (6.00%) 6 | 2 / 102 (1.96%) 2 | 5 / 103 (4.85%) 9 |
| Fatigue subjects affected / exposed occurrences (all) | 1 / 100 (1.00%) 1 | 4 / 102 (3.92%) 5 | 3 / 103 (2.91%) 3 |
| Influenza like illness subjects affected / exposed occurrences (all) | 2 / 100 (2.00%) 4 | 0 / 102 (0.00%) 0 | 0 / 103 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 4 / 100 (4.00%) 4 | 4 / 102 (3.92%) 4 | 4 / 103 (3.88%) 5 |
| Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all) | 2 / 100 (2.00%) 2 | 6 / 102 (5.88%) 7 | 7 / 103 (6.80%) 7 |
| Gastrointestinal disorders Abdominal distension subjects affected / exposed occurrences (all) | 1 / 100 (1.00%) 1 | 0 / 102 (0.00%) 0 | 0 / 103 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | 6 / 100 (6.00%) 6 | 0 / 102 (0.00%) 0 | 0 / 103 (0.00%) 0 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 100 (0.00%) 0 | 1 / 102 (0.98%) 3 | 0 / 103 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 1 / 100 (1.00%) 1 | 1 / 102 (0.98%) 1 | 0 / 103 (0.00%) 0 |

| | | | |
|--|----------------------|----------------------|-----------------------|
| Diarrhoea subjects affected / exposed occurrences (all) | 1 / 100 (1.00%) 1 | 1 / 102 (0.98%) 1 | 0 / 103 (0.00%) 0 |
| Dyspepsia subjects affected / exposed occurrences (all) | 3 / 100 (3.00%) 3 | 1 / 102 (0.98%) 1 | 3 / 103 (2.91%) 3 |
| Nausea subjects affected / exposed occurrences (all) | 6 / 100 (6.00%) 7 | 6 / 102 (5.88%) 7 | 7 / 103 (6.80%) 8 |
| Vomiting subjects affected / exposed occurrences (all) | 0 / 100 (0.00%) 0 | 3 / 102 (2.94%) 3 | 5 / 103 (4.85%) 5 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 4 / 100 (4.00%) 4 | 2 / 102 (1.96%) 2 | 5 / 103 (4.85%) 10 |
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 100 (0.00%) 0 | 0 / 102 (0.00%) 0 | 1 / 103 (0.97%) 1 |
| Skin and subcutaneous tissue disorders Dermal cyst subjects affected / exposed occurrences (all) | 0 / 100 (0.00%) 0 | 0 / 102 (0.00%) 0 | 0 / 103 (0.00%) 0 |
| Rash erythematous subjects affected / exposed occurrences (all) | 0 / 100 (0.00%) 0 | 0 / 102 (0.00%) 0 | 0 / 103 (0.00%) 0 |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) | 1 / 100 (1.00%) 1 | 1 / 102 (0.98%) 1 | 2 / 103 (1.94%) 2 |
| Depression subjects affected / exposed occurrences (all) | 0 / 100 (0.00%) 0 | 1 / 102 (0.98%) 1 | 0 / 103 (0.00%) 0 |
| Insomnia subjects affected / exposed occurrences (all) | 2 / 100 (2.00%) 3 | 2 / 102 (1.96%) 2 | 2 / 103 (1.94%) 2 |

| | | | |
|---|-----------------|-----------------|------------------|
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 6 / 100 (6.00%) | 3 / 102 (2.94%) | 4 / 103 (3.88%) |
| occurrences (all) | 6 | 3 | 5 |
| Back pain | | | |
| subjects affected / exposed | 2 / 100 (2.00%) | 2 / 102 (1.96%) | 4 / 103 (3.88%) |
| occurrences (all) | 2 | 2 | 5 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 2 / 103 (1.94%) |
| occurrences (all) | 0 | 0 | 2 |
| Myalgia | | | |
| subjects affected / exposed | 2 / 100 (2.00%) | 2 / 102 (1.96%) | 2 / 103 (1.94%) |
| occurrences (all) | 2 | 3 | 2 |
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 0 / 102 (0.00%) | 1 / 103 (0.97%) |
| occurrences (all) | 1 | 0 | 1 |
| Infections and infestations | | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 1 / 102 (0.98%) | 0 / 103 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Genital candidiasis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 2 / 103 (1.94%) |
| occurrences (all) | 0 | 0 | 2 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 5 / 100 (5.00%) | 4 / 102 (3.92%) | 10 / 103 (9.71%) |
| occurrences (all) | 8 | 4 | 11 |
| Oral herpes | | | |
| subjects affected / exposed | 2 / 100 (2.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 2 / 102 (1.96%) | 0 / 103 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Rhinitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 1 / 103 (0.97%) |
| occurrences (all) | 0 | 0 | 5 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 1 / 103 (0.97%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 2 / 103 (1.94%) |
| occurrences (all) | 0 | 0 | 2 |
| Urinary tract infection | | | |
| subjects affected / exposed | 3 / 100 (3.00%) | 1 / 102 (0.98%) | 2 / 103 (1.94%) |
| occurrences (all) | 3 | 1 | 2 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 100 (0.00%) | 0 / 102 (0.00%) | 0 / 103 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | MP: Placebo to Placebo | MP: BMS-936557 to Placebo | MP: BMS-936557 5 mg/kg |
|---|------------------------|---------------------------|------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 14 / 30 (46.67%) | 13 / 22 (59.09%) | 16 / 24 (66.67%) |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 2 / 30 (6.67%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 22 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 1 | 0 | 2 |
| Headache | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 3 / 22 (13.64%) | 5 / 24 (20.83%) |
| occurrences (all) | 0 | 3 | 28 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 30 (0.00%) 0 | 2 / 22 (9.09%) 2 | 0 / 24 (0.00%) 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 3 / 30 (10.00%) | 1 / 22 (4.55%) | 0 / 24 (0.00%) |
| occurrences (all) | 6 | 2 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 22 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 0 | 1 |
| Influenza like illness | | | |
| subjects affected / exposed | 3 / 30 (10.00%) | 2 / 22 (9.09%) | 2 / 24 (8.33%) |
| occurrences (all) | 7 | 2 | 3 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 4 / 22 (18.18%) | 3 / 24 (12.50%) |
| occurrences (all) | 1 | 8 | 3 |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 4 / 30 (13.33%) | 0 / 22 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 9 | 0 | 2 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 22 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 0 | 1 |
| Constipation | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 2 / 22 (9.09%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 6 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Dyspepsia | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 2 / 30 (6.67%) 2 | 0 / 22 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Nausea subjects affected / exposed occurrences (all) | 1 / 30 (3.33%) 1 | 0 / 22 (0.00%) 0 | 2 / 24 (8.33%) 7 |
| Vomiting subjects affected / exposed occurrences (all) | 1 / 30 (3.33%) 1 | 1 / 22 (4.55%) 1 | 0 / 24 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 0 / 30 (0.00%) 0 | 1 / 22 (4.55%) 1 | 6 / 24 (25.00%) 7 |
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 30 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Skin and subcutaneous tissue disorders Dermal cyst subjects affected / exposed occurrences (all) | 0 / 30 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Rash erythematous subjects affected / exposed occurrences (all) | 0 / 30 (0.00%) 0 | 0 / 22 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) | 1 / 30 (3.33%) 1 | 1 / 22 (4.55%) 1 | 1 / 24 (4.17%) 1 |
| Depression subjects affected / exposed occurrences (all) | 0 / 30 (0.00%) 0 | 0 / 22 (0.00%) 0 | 2 / 24 (8.33%) 2 |
| Insomnia subjects affected / exposed occurrences (all) | 0 / 30 (0.00%) 0 | 1 / 22 (4.55%) 2 | 2 / 24 (8.33%) 2 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 5 / 30 (16.67%) 6 | 3 / 22 (13.64%) 3 | 5 / 24 (20.83%) 6 |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Back pain | | | |
| subjects affected / exposed | 2 / 30 (6.67%) | 0 / 22 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 3 | 0 | 2 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Infections and infestations | | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 2 / 22 (9.09%) | 3 / 24 (12.50%) |
| occurrences (all) | 0 | 2 | 4 |
| Genital candidiasis | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Influenza | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 22 (4.55%) | 6 / 24 (25.00%) |
| occurrences (all) | 0 | 1 | 8 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 4 / 30 (13.33%) | 1 / 22 (4.55%) | 2 / 24 (8.33%) |
| occurrences (all) | 7 | 1 | 4 |
| Oral herpes | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 22 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 2 / 30 (6.67%) | 2 / 22 (9.09%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 2 / 30 (6.67%) | 0 / 22 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 2 | 0 | 1 |
| Sinusitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 30 (3.33%) | 2 / 22 (9.09%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 1 / 22 (4.55%) | 2 / 24 (8.33%) |
| occurrences (all) | 1 | 1 | 2 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 30 (3.33%) | 1 / 22 (4.55%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 22 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |

| Non-serious adverse events | MP: BMS-936557 10 mg/kg | MP: BMS-936557 20 mg/kg | OL: BMS-936557 10 mg/kg |
|---|-------------------------|-------------------------|-------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 17 / 22 (77.27%) | 13 / 21 (61.90%) | 149 / 237 (62.87%) |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 0 | 2 |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 13 / 237 (5.49%) |
| occurrences (all) | 0 | 0 | 16 |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 7 / 237 (2.95%) |
| occurrences (all) | 0 | 0 | 9 |
| Headache | | | |
| subjects affected / exposed | 6 / 22 (27.27%) | 3 / 21 (14.29%) | 23 / 237 (9.70%) |
| occurrences (all) | 16 | 4 | 51 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 13 / 237 (5.49%) |
| occurrences (all) | 0 | 0 | 13 |
| General disorders and administration site conditions | | | |

| | | | |
|-----------------------------|----------------|-----------------|------------------|
| Asthenia | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 21 (0.00%) | 8 / 237 (3.38%) |
| occurrences (all) | 1 | 0 | 18 |
| Fatigue | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 21 (0.00%) | 11 / 237 (4.64%) |
| occurrences (all) | 2 | 0 | 12 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 21 (0.00%) | 8 / 237 (3.38%) |
| occurrences (all) | 1 | 0 | 10 |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 2 / 21 (9.52%) | 20 / 237 (8.44%) |
| occurrences (all) | 3 | 2 | 21 |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 3 / 21 (14.29%) | 7 / 237 (2.95%) |
| occurrences (all) | 1 | 5 | 11 |
| Gastrointestinal disorders | | | |
| Abdominal distension | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 21 (0.00%) | 3 / 237 (1.27%) |
| occurrences (all) | 2 | 0 | 3 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 1 / 21 (4.76%) | 15 / 237 (6.33%) |
| occurrences (all) | 0 | 1 | 20 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 2 / 21 (9.52%) | 6 / 237 (2.53%) |
| occurrences (all) | 0 | 3 | 6 |
| Constipation | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 0 | 2 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 21 (0.00%) | 7 / 237 (2.95%) |
| occurrences (all) | 1 | 0 | 9 |
| Dyspepsia | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 21 (0.00%) | 16 / 237 (6.75%) |
| occurrences (all) | 2 | 0 | 19 |
| Nausea | | | |

| | | | |
|---|----------------------|---------------------|------------------------|
| subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 0 / 21 (0.00%) 0 | 15 / 237 (6.33%) 24 |
| Vomiting subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 2 | 0 / 21 (0.00%) 0 | 8 / 237 (3.38%) 13 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 3 / 22 (13.64%) 4 | 2 / 21 (9.52%) 2 | 12 / 237 (5.06%) 13 |
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 2 / 21 (9.52%) 2 | 4 / 237 (1.69%) 5 |
| Skin and subcutaneous tissue disorders Dermal cyst subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 2 | 0 / 21 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Rash erythematous subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 2 | 0 / 21 (0.00%) 0 | 1 / 237 (0.42%) 2 |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 2 | 0 / 21 (0.00%) 0 | 6 / 237 (2.53%) 7 |
| Depression subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 0 / 21 (0.00%) 0 | 3 / 237 (1.27%) 4 |
| Insomnia subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 21 (0.00%) 0 | 3 / 237 (1.27%) 5 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 3 / 22 (13.64%) 4 | 0 / 21 (0.00%) 0 | 21 / 237 (8.86%) 35 |
| Back pain subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 1 / 21 (4.76%) 1 | 14 / 237 (5.91%) 19 |

| | | | |
|--|----------------------|---------------------|-------------------------|
| Musculoskeletal pain subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 3 | 2 / 21 (9.52%) 2 | 1 / 237 (0.42%) 1 |
| Myalgia subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 0 / 21 (0.00%) 0 | 6 / 237 (2.53%) 6 |
| Pain in extremity subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 0 / 21 (0.00%) 0 | 4 / 237 (1.69%) 4 |
| Infections and infestations | | | |
| Gastroenteritis subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 2 | 1 / 21 (4.76%) 1 | 12 / 237 (5.06%) 16 |
| Genital candidiasis subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Influenza subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 2 | 1 / 21 (4.76%) 2 | 9 / 237 (3.80%) 12 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 3 / 22 (13.64%) 5 | 0 / 21 (0.00%) 0 | 39 / 237 (16.46%) 65 |
| Oral herpes subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 5 | 0 / 21 (0.00%) 0 | 5 / 237 (2.11%) 7 |
| Pharyngitis subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 2 / 21 (9.52%) 2 | 5 / 237 (2.11%) 7 |
| Rhinitis subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 21 (4.76%) 1 | 3 / 237 (1.27%) 5 |
| Sinusitis subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 21 (0.00%) 0 | 9 / 237 (3.80%) 12 |
| Upper respiratory tract infection | | | |

| | | | |
|---|-----------------|----------------|-------------------|
| subjects affected / exposed | 3 / 22 (13.64%) | 2 / 21 (9.52%) | 24 / 237 (10.13%) |
| occurrences (all) | 5 | 2 | 31 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 14 / 237 (5.91%) |
| occurrences (all) | 0 | 0 | 17 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 21 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 20 June 2011 | <ul style="list-style-type: none">• Added Drug-induced liver injury language.• Deleted 84 and 112 days post dosing visits.• Deleted requirement for male contraception.• Exclusion Criteria were modified to be more specific, Added "Lichtiger score of ≥ 10 and Subjects with evidence of active CMV (cytomegalovirus) infection or CMV colitis should also be excluded from the study".• Added vital signs to each clinic and infusion visit in the T&E.• Added storage time for biopsy and exploratory biomarkers samples.• Revised to indicate a Physician's Assistant can perform the Complete Physical Exam and the PGA for the Full Mayo Score.• Deleted creatinine from the urinalysis testing.• Added information that the diary entries should be collected prior to the preparation day for the endoscopy.• Added two secondary endpoints to match secondary objectives. |
| 20 October 2011 | <ul style="list-style-type: none">• Changed the duration of the Induction Period (IP) to be 11 weeks and the primary endpoint to IP-78 throughout the protocol.• Changed Post Dosing Follow-up Visit from 14 days post last dose to 28 days.• Specified criteria for dose decrease and limited the option to decrease the dose to 10 mg/kg only during Open-Label.• Clarified requirements and procedures for drug administration. |
| 19 March 2013 | <ul style="list-style-type: none">• Added severe and/or serious acute infusion reactions as a reason for discontinuation.• Clarified the infusion rate for induction period, maintenance Phase, and open label period. |
| 16 December 2013 | <ul style="list-style-type: none">• Allowed all subjects to enter open label period regardless of clinical remission or relapse. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The sponsor decided not to pursue further clinical development of BMS-936557 due to an insufficient demonstration of efficacy across studies in Inflammatory Bowel Disease .

Notes: