# Clinical trial results:
# Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Pharmacodynamics, Safety and Pharmacokinetics of BMS-955176 (Double-Blinded) and BMS-955176 with Atazanavir +/- Ritonavir (Open-Labeled) in HIV-1 Infected Subjects

## Summary

| | |
|---|---|
| EudraCT number | 2012-004124-38 |
| Trial protocol | DE GB |
| Global end of trial date | 29 November 2014 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 29 July 2016 |
| First version publication date | 29 July 2016 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | AI468-002 |

**Additional study identifiers**

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

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Bristol-Myers Squibb |
| Sponsor organisation address | Chaussee 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 | 29 November 2014 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 29 November 2014 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

Primary Objective was to assess the antiviral activity in HIV-1 infected subjects following administration of BMS-955176 for 10 days.

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 | 04 April 2013 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | South Africa: 46 |
| Country: Number of subjects enrolled | United Kingdom: 6 |
| Country: Number of subjects enrolled | Germany: 139 |
| Worldwide total number of subjects | 191 |
| EEA total number of subjects | 145 |

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) | 191 |
| From 65 to 84 years | 0 |

| | |
|---|---|
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted at 3 centres in 3 countries.

### Pre-assignment

Screening details:

Out of 191 subjects enrolled only 107 subjects (Part A: 60 subjects; Part B: 28 subjects; and Part C: 19 subjects) received treatment during the study, 84 subjects had not received treatment due to various reasons as: Subject Withdrew Consent-3, Pregnancy-3, Subject No Longer Meets Study Criteria-73 and Other-5.

### Period 1

| | |
|---|---|
| Period 1 title | Part A (HIV-1 Clade B) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Investigator, Monitor, Data analyst, Carer, Subject, Assessor |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Part A-Group 1: BMS-955176 (5 mg) |

Arm description:

Subjects infected with HIV-1 clade B were treated with 5 mg BMS-955176 as oral suspension, once daily (QD) from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 5 mg BMS-955176 as oral suspension, QD.

| | |
|---|---|
| **Arm title** | Part A-Group 2: BMS-955176 (10 mg) |

Arm description:

Subjects infected with HIV-1 clade B were treated with 10 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 10 mg BMS-955176 as oral suspension, QD.

| | |
|---|---|
| **Arm title** | Part A-Group 3: BMS-955176 (20 mg) |

Arm description:

Subjects infected with HIV-1 clade B were treated with 20 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

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

| | |
|---|---|
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 20 mg BMS-955176 as oral suspension, QD.

| **Arm title** | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|

Arm description:

Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 40 mg BMS-955176 as oral suspension, QD.

| **Arm title** | Part A-Group 9: BMS-955176 (80 mg) |
|---|---|

Arm description:

Subjects infected with HIV-1 clade B were treated with 80 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10 under fasting condition. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 80 mg BMS-955176 as oral suspension, QD.

| **Arm title** | Part A-Group 10: BMS-955176 (120 mg) |
|---|---|

Arm description:

Subjects infected with HIV-1 clade B were treated with 120 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10 under fasting condition. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 120 mg BMS-955176 as oral suspension, QD.

| **Arm title** | Placebo Clade B |
|---|---|

Arm description:

Subjects infected with HIV-1 clade B were treated with matching placebo QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose,

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

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

Dosage and administration details:

Subjects were treated with matching placebo QD.

| **Number of subjects in period 1[1]** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) |
|---|---|---|---|
| Started | 8 | 8 | 8 |
| Completed | 8 | 8 | 8 |

| **Number of subjects in period 1[1]** | Part A-Group 4: BMS-955176 (40 mg) | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) |
|---|---|---|---|
| Started | 8 | 8 | 8 |
| Completed | 8 | 8 | 8 |

| **Number of subjects in period 1[1]** | Placebo Clade B |
|---|---|
| Started | 12 |
| Completed | 12 |

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: Out of 191 subjects who were enrolled, 107 subjects were randomised and were distributed in the 3 parts of the study; Part A: 60 subjects; Part B: 28 subjects; and Part C: 19 subjects.

## Period 2

| | |
|---|---|
| Period 2 title | Part B (HIV-1 Clade B) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

## Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir |

Arm description:

Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension and 400 mg atazanavir (2*200 mg) capsules, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose.

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

| | |
|---|---|
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 40 mg BMS-955176 as oral suspension, QD.

| | |
|---|---|
| Investigational medicinal product name | Atazanavir |
| Investigational medicinal product code | |
| Other name | Reyataz™ |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 400 mg Atazanavir as capsules, QD.

| | |
|---|---|
| **Arm title** | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |

Arm description:

Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension, 300 mg atazanavir capsules and 100 mg ritonavir tablets, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Ritonavir |
| Investigational medicinal product code | |
| Other name | Norvir™ |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 100 mg Ritonavir tablet orally, QD.

| | |
|---|---|
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 40 mg BMS-955176 as oral suspension, QD.

| | |
|---|---|
| Investigational medicinal product name | Atazanavir |
| Investigational medicinal product code | |
| Other name | Reyataz™ |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 300 mg Atazanavir as capsules, QD.

| | |
|---|---|
| **Arm title** | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine |

Arm description:

Subjects infected with HIV-1 clade B were treated with 300 mg tenofovir, 200 mg emtricitabine, 300 mg atazanavir capsules and 100 mg ritonavir tablets, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Tenofovir |
| Investigational medicinal product code | |
| Other name | Viread™ |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 300 mg Tenofovir orally, QD.

| | |
|---|---|
| Investigational medicinal product name | Emtricitabine |
| Investigational medicinal product code | |
| Other name | Emtriva™ |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 200 mg Emtricitabine orally, QD.

| | |
|---|---|
| Investigational medicinal product name | Atazanavir |
| Investigational medicinal product code | |
| Other name | Reyataz™ |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 300 mg Atazanavir as capsules, QD.

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

Dosage and administration details:

Subjects were treated with 100 mg Ritonavir tablet orally, QD.

| | |
|---|---|
| **Arm title** | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir |

Arm description:

Subjects infected with HIV-1 clade B were treated with 80 mg BMS-955176 as oral suspension and 400 mg atazanavir (2*200 mg) capsules, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 80 mg BMS-955176 as oral suspension, QD.

| | |
|---|---|
| Investigational medicinal product name | Atazanavir |
| Investigational medicinal product code | |
| Other name | Reyataz™ |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 400 mg Atazanavir as capsules, QD.

| Number of subjects in period 2[2] | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine |
|---|---|---|---|
| Started | 8 | 8 | 4 |
| Completed | 8 | 8 | 4 |

| Number of subjects in period 2[2] | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir |
|---|---|
| Started | 8 |
| Completed | 8 |

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: 107 subjects were randomised and were distributed in the 3 parts of the study; Part A: 60 subjects; Part B: 28 subjects; and Part C: 19 subjects.

## Period 3

| | |
|---|---|
| Period 3 title | Part C (HIV-1 Clade C only) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |

## Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Part C-Group 8: BMS-955176 (40 mg) |

Arm description:

Subjects infected with HIV-1 clade C were treated with 40 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 40 mg BMS-955176 as oral suspension, QD.

| | |
|---|---|
| **Arm title** | Part C-Group 13: BMS-955176 (120 mg) |

Arm description:

Subjects infected with HIV-1 clade C were treated with 120 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-955176 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral suspension |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were treated with 120 mg BMS-955176 as oral suspension, QD.

| **Arm title** | Placebo Clade C |
|---|---|

Arm description:

Subjects infected with HIV-1 clade C were treated with matching placebo, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

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

Dosage and administration details:

Subjects were treated with matching placebo QD.

| **Number of subjects in period 3[3]** | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) | Placebo Clade C |
|---|---|---|---|
| Started | 8 | 7 | 4 |
| Completed | 8 | 7 | 4 |

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: A total of 107 subjects were randomised and were distributed in the 3 parts of the study; Part A: 60 subjects; Part B: 28 subjects; and Part C: 19 subjects

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Part A-Group 1: BMS-955176 (5 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 5 mg BMS-955176 as oral suspension, once daily (QD) from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 2: BMS-955176 (10 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 10 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 3: BMS-955176 (20 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 20 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 4: BMS-955176 (40 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 9: BMS-955176 (80 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 80 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10 under fasting condition. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 10: BMS-955176 (120 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 120 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10 under fasting condition. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Placebo Clade B |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with matching placebo QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose, | |

| Reporting group values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) |
|---|---|---|---|
| Number of subjects | 8 | 8 | 8 |
| Age categorical | | | |
| Units: Subjects | | | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 41.6 | 37.5 | 33.3 |
| standard deviation | ± 8.73 | ± 11.07 | ± 7.19 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 0 | 1 | 0 |
| Male | 8 | 7 | 8 |

| Reporting group values | Part A-Group 4: BMS-955176 (40 mg) | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Number of subjects | 8 | 8 | 8 |
| Age categorical<br>Units: Subjects | | | |

| | | | |
|---|---|---|---|
| Age continuous<br>Units: years | | | |
| arithmetic mean | 39.5 | 36.3 | 38 |
| standard deviation | ± 8.09 | ± 11.23 | ± 9.49 |
| Gender categorical<br>Units: Subjects | | | |
| Female | 0 | 0 | 0 |
| Male | 8 | 8 | 8 |

| **Reporting group values** | Placebo Clade B | Total | |
|---|---|---|---|
| Number of subjects | 12 | 60 | |
| Age categorical<br>Units: Subjects | | | |

| | | | |
|---|---|---|---|
| Age continuous<br>Units: years | | | |
| arithmetic mean | 36.3 | | |
| standard deviation | ± 7.12 | - | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 0 | 1 | |
| Male | 12 | 59 | |

## End points

### End points reporting groups

| Reporting group title | Part A-Group 1: BMS-955176 (5 mg) |
|---|---|
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 5 mg BMS-955176 as oral suspension, once daily (QD) from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 2: BMS-955176 (10 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 10 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 3: BMS-955176 (20 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 20 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 4: BMS-955176 (40 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 9: BMS-955176 (80 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 80 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10 under fasting condition. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Part A-Group 10: BMS-955176 (120 mg) |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 120 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10 under fasting condition. Subjects were evaluated for a total period of 24 days from the day of first dose. | |
| Reporting group title | Placebo Clade B |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with matching placebo QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose, | |
| Reporting group title | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension and 400 mg atazanavir (2*200 mg) capsules, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose. | |
| Reporting group title | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension, 300 mg atazanavir capsules and 100 mg ritonavir tablets, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose. | |
| Reporting group title | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 300 mg tenofovir, 200 mg emtricitabine, 300 mg atazanavir capsules and 100 mg ritonavir tablets, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose. | |
| Reporting group title | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir |
| Reporting group description: | |
| Subjects infected with HIV-1 clade B were treated with 80 mg BMS-955176 as oral suspension and 400 mg atazanavir (2*200 mg) capsules, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose. | |
| Reporting group title | Part C-Group 8: BMS-955176 (40 mg) |

Reporting group description:

Subjects infected with HIV-1 clade C were treated with 40 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| Reporting group title | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|

Reporting group description:

Subjects infected with HIV-1 clade C were treated with 120 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| Reporting group title | Placebo Clade C |
|---|---|

Reporting group description:

Subjects infected with HIV-1 clade C were treated with matching placebo, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

## Primary: Change in Plasma Log10 HIV-1 Ribonucleic Acid (RNA) Levels from Baseline to Day 11

| End point title | Change in Plasma Log10 HIV-1 Ribonucleic Acid (RNA) Levels from Baseline to Day 11[1] |
|---|---|

End point description:

Antiviral activity of BMS-955176 was estimated by measuring the plasma HIV-1 RNA levels in the HIV-1 infected subjects. Change in the plasma HIV-1 RNA levels were measured in the subjects infected with HIV-1 clade B and C who undergone BMS-955176 monotherapy. The analysis was performed in all treated subjects who had received at least one dose of study drug.

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

End point timeframe:

Baseline and Day 11 after the final dose with BMS-955176

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed.

| **End point values** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: copies per millilitre (c/mL) | | | | |
| arithmetic mean (standard deviation) | -0.138 (± 0.1281) | -0.567 (± 0.5845) | -0.889 (± 0.6582) | -1.279 (± 0.4596) |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: copies per millilitre (c/mL) | | | | |
| arithmetic mean (standard deviation) | -1.339 (± 0.29) | -1.326 (± 0.3855) | -1.216 (± 0.4366) | -1.431 (± 0.2967) |

| End point values | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: copies per millilitre (c/mL) | | | | |
| arithmetic mean (standard deviation) | -1.544 (± 0.4155) | -1.521 (± 0.2651) | -1.29 (± 0.3376) | -0.938 (± 0.6897) |

| End point values | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: copies per millilitre (c/mL) | | | | |
| arithmetic mean (standard deviation) | 0.118 (± 0.5277) | -0.172 (± 0.7876) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Reach Maximum Plasma Concentration (Tmax) - Part A and C

| End point title | Time to Reach Maximum Plasma Concentration (Tmax) - Part A and C[2] |
|---|---|

End point description:

Time to reach the maximum plasma concentration was directly determined from concentration time data. The analysis was performed in all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Pre-dose Day 1 to Day 10

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to evaluate for the specified arm only.

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Hours | | | | |
| median (full range (min-max)) | | | | |

| | | | | |
|---|---|---|---|---|
| Day 1 | 3 (1.5 to 6) | 2.51 (2 to 4) | 3 (3 to 6) | 4 (2 to 6) |
| Day 10 | 3 (2 to 4) | 3 (1.5 to 4) | 4 (3 to 16) | 3 (2 to 6) |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 7 |
| Units: Hours | | | | |
| median (full range (min-max)) | | | | |
| Day 1 | 3.5 (3 to 4) | 3 (1.5 to 6) | 3.5 (2 to 10) | 3.53 (2 to 4.25) |
| Day 10 | 3 (1.5 to 4.02) | 2.5 (1.5 to 3.87) | 3 (2 to 6) | 3 (1.55 to 4) |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Number of Subjects With Death as Outcome, Serious Adverse Events (SAEs), Related SAEs, Discontinuations Due to SAEs, Adverse Events (AEs), and Discontinuations Due to AEs During the study**

| | |
|---|---|
| End point title | Number of Subjects With Death as Outcome, Serious Adverse Events (SAEs), Related SAEs, Discontinuations Due to SAEs, Adverse Events (AEs), and Discontinuations Due to AEs During the study |

End point description:

AE=any new unfavorable symptom, sign, or disease or worsening of a preexisting condition that may not have a causal relationship with treatment. SAE=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. Related=having certain, probable, possible, or unknown relationship to study drug. Analysis was performed in all the randomised subjects who received at least 1 dose of double-blind study medication in the Treatment Period.

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

End point timeframe:

Day 1 to up to end of the study (Day 42)

| **End point values** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: subjects | | | | |
| Deaths | 0 | 0 | 0 | 0 |
| SAEs | 0 | 0 | 0 | 0 |
| Related SAEs | 0 | 0 | 0 | 0 |

| | | | | |
|---|---|---|---|---|
| Discontinuations due to SAEs | 0 | 0 | 0 | 0 |
| Discontinuations due to AEs | 0 | 0 | 0 | 0 |
| AEs | 5 | 5 | 5 | 6 |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: subjects | | | | |
| Deaths | 0 | 0 | 0 | 0 |
| SAEs | 0 | 0 | 0 | 0 |
| Related SAEs | 0 | 0 | 0 | 0 |
| Discontinuations due to SAEs | 0 | 0 | 0 | 0 |
| Discontinuations due to AEs | 0 | 0 | 0 | 0 |
| AEs | 8 | 7 | 8 | 8 |

| **End point values** | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: subjects | | | | |
| Deaths | 0 | 0 | 0 | 0 |
| SAEs | 0 | 0 | 0 | 0 |
| Related SAEs | 0 | 0 | 0 | 0 |
| Discontinuations due to SAEs | 0 | 0 | 0 | 0 |
| Discontinuations due to AEs | 0 | 0 | 0 | 0 |
| AEs | 4 | 6 | 7 | 6 |

| **End point values** | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: subjects | | | | |
| Deaths | 0 | 0 | | |
| SAEs | 0 | 0 | | |
| Related SAEs | 0 | 0 | | |
| Discontinuations due to SAEs | 0 | 0 | | |
| Discontinuations due to AEs | 0 | 0 | | |
| AEs | 9 | 3 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Maximum Decline from Baseline in Log10 HIV-1 Ribonucleic Acid (RNA)

| End point title | Maximum Decline from Baseline in Log10 HIV-1 Ribonucleic Acid (RNA) |
|---|---|

End point description:

Antiviral activity of BMS-955176 was estimated by measuring the plasma HIV-1 RNA levels in the HIV-1 infected subjects. Maximum decline from baseline in the plasma HIV-1 RNA levels were measured in the subjects infected with HIV-1 clade B and C. The analysis was performed in all treated subjects who had received at least one dose of study drug.

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

End point timeframe:

Part A and C: Baseline up to Day 24; Part B: Baseline up to Day 42

| **End point values** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: c/mL | | | | |
| median (full range (min-max)) | -0.498 (-0.78 to -0.22) | -0.976 (-1.76 to -0.64) | -1.115 (-2.12 to -0.13) | -1.701 (-1.88 to -0.93) |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: c/mL | | | | |
| median (full range (min-max)) | -1.555 (-1.82 to -1.04) | -1.654 (-2.07 to -0.83) | -1.858 (-2.37 to -1.49) | -2.202 (-3.52 to -1.24) |

| **End point values** | Part B-Group 7: Atazanavir+Ritonavir+Tenofo | Part B-Group 12: BMS-955176 (80 mg) + | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|

| | vir+Emtricitabine | Atazanavir | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: c/mL | | | | |
| median (full range (min-max)) | -2.39 (-3.04 to -1.83) | -2.228 (-2.68 to -1.87) | -1.352 (-2.03 to -1.04) | -1.257 (-2.02 to -0.7) |

| **End point values** | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: c/mL | | | | |
| median (full range (min-max)) | -0.381 (-1.46 to 0.56) | -0.419 (-1.21 to 0.22) | | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Time to Maximum Decline in Log 10 HIV-1 Ribonucleic Acid (RNA)**

| End point title | Time to Maximum Decline in Log 10 HIV-1 Ribonucleic Acid (RNA) |
|---|---|

End point description:

Antiviral activity of BMS-955176 was estimated by measuring the plasma HIV-1 RNA levels in the HIV-1 infected subjects. Time to maximum decline in the plasma HIV-1 RNA levels were measured in the subjects infected with HIV-1 clade B and C. The analysis was performed in all treated subjects who had received at least one dose of study drug.

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

End point timeframe:

Part A and C: Baseline up to Day 24; Part B: Baseline up to Day 42

| **End point values** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Hours | | | | |
| median (full range (min-max)) | 168 (72 to 433.4) | 216 (48 to 553.5) | 203.9 (168 to 288.1) | 240.15 (120.1 to 312.1) |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + | Part B-Group 6: BMS-955176 (40 mg) + |
|---|---|---|---|---|

| | | | Atazanavir | Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Hours | | | | |
| median (full range (min-max)) | 204 (168 to 384.6) | 240.2 (216 to 288.3) | 624 (360 to 816.3) | 636.05 (216 to 816.9) |

| **End point values** | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: Hours | | | | |
| median (full range (min-max)) | 588 (528 to 672.1) | 636.05 (528 to 816.3) | 228.05 (192 to 384.6) | 215.8 (120 to 312) |

| **End point values** | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: Hours | | | | |
| median (full range (min-max)) | 216.2 (24 to 433.8) | 132.05 (23.9 to 786.3) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Cluster of Differentiation (CD) 4+ and CD8+ Lymphocyte Counts

| End point title | Change From Baseline in Cluster of Differentiation (CD) 4+ and CD8+ Lymphocyte Counts |
|---|---|

End point description:

Change in the CD4+ and CD8+ cell counts from baseline were measured in the subjects infected with HIV-1 clade B and C who undergone BMS-955176 + ATV or BMS-955176 + ATV + RTV therapy. The analysis was performed in all treated subjects who had received at least one dose of study drug. Here 'n' signifies number of subjects evaluable for this endpoint at specified time points.

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

End point timeframe:

Part A and C: Baseline up to Day 24; Part B: Baseline up to Day 42

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Cells/microlitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+ (n = 6,7,7,7,8,7,5,7,4,4,6,6,9,4) | -21.8 (± 88.37) | 14.6 (± 120.82) | -70.1 (± 68.49) | -23.6 (± 42.13) |
| CD8+ (n = 6,7,7,7,8,7,5,7,4,4,6,6,9,4) | -95 (± 301.52) | -8.3 (± 236.48) | -107.4 (± 264.26) | -57.3 (± 126.25) |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Cells/microlitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+ (n = 6,7,7,7,8,7,5,7,4,4,6,6,9,4) | -43.8 (± 69.5) | -56.7 (± 78.26) | -133.2 (± 84.14) | -106.4 (± 166.59) |
| CD8+ (n = 6,7,7,7,8,7,5,7,4,4,6,6,9,4) | -194.6 (± 182.3) | -161.3 (± 203.01) | -442.8 (± 243.99) | -466.1 (± 491.21) |

| End point values | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: Cells/microlitre | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+ (n = 6,7,7,7,8,7,5,7,4,4,6,6,9,4) | 33 (± 144.79) | -89 (± 35.71) | -53.7 (± 93.76) | 24.5 (± 57.58) |
| CD8+ (n = 6,7,7,7,8,7,5,7,4,4,6,6,9,4) | -216.3 (± 287.06) | -147 (± 140.67) | -214.4 (± 390.13) | -155.8 (± 56.55) |

| End point values | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: Cells/microlitre | | | | |
| arithmetic mean (standard deviation) | | | | |

| | | | | |
|---|---|---|---|---|
| CD4+ (n = 6,7,7,7,8,7,5,7,4,4,6,6,9,4) | -77.3 (± 91.05) | 18 (± 67.3) | | |
| CD8+ (n = 6,7,7,7,8,7,5,7,4,4,6,6,9,4) | -93.1 (± 138.52) | -136.3 (± 224.49) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Cluster of Differentiation (CD) 4+ and CD8+ Lymphocyte Percent

| End point title | Change From Baseline in Cluster of Differentiation (CD) 4+ and CD8+ Lymphocyte Percent |
|---|---|

End point description:

Percent Change in the CD4+ and CD8+ cell counts from baseline were measured in the subjects infected with HIV-1 clade B and C who undergone BMS-955176 + ATV or BMS-955176 + ATV + RTV therapy. The analysis was performed in all treated subjects who had received at least one dose of study drug. Here 'n' signifies number of subjects evaluable for this endpoint at specified time points.

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

End point timeframe:

Part A and C: Baseline up to Day 24; Part B: Baseline up to Day 42

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Percent change | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+ (n = 6,7,7,7,8,7,5,8,4,4,6,6,9,4) | 2.33 (± 2.944) | 0.29 (± 2.215) | -1.29 (± 5.057) | 0.86 (± 3.288) |
| CD8+ (n = 6,7,7,7,8,7,5,8,4,4,6,6,9,4) | 1.17 (± 2.401) | 0.43 (± 3.207) | 0 (± 6.325) | 1 (± 3.225) |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Percent change | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+ (n = 6,7,7,7,8,7,5,8,4,4,6,6,9,4) | 2.13 (± 3.399) | 0.29 (± 2.87) | 2.4 (± 2.881) | 3.25 (± 3.105) |
| CD8+ (n = 6,7,7,7,8,7,5,8,4,4,6,6,9,4) | -0.25 (± 5.064) | -2.29 (± 2.812) | -2.8 (± 1.924) | -6.25 (± 4.464) |

| End point values | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: Percent change | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+ (n = 6,7,7,7,8,7,5,8,4,4,6,6,9,4) | 4.75 (± 2.217) | -0.75 (± 1.893) | 0.5 (± 3.017) | 3.17 (± 3.371) |
| CD8+ (n = 6,7,7,7,8,7,5,8,4,4,6,6,9,4) | -3.75 (± 2.062) | -1.25 (± 2.217) | 0 (± 1.871) | -4.25 (± 3.775) |

| End point values | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: Percent change | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+ (n = 6,7,7,7,8,7,5,8,4,4,6,6,9,4) | -0.22 (± 3.93) | 2.75 (± 3.775) | | |
| CD8+ (n = 6,7,7,7,8,7,5,8,4,4,6,6,9,4) | 1.75 (± 4.2) | -1.33 (± 5.132) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Reach Maximum Plasma Concentration (Tmax) - Part B

| End point title | Time to Reach Maximum Plasma Concentration (Tmax) - Part B |
|---|---|

End point description:

Tmax was directly determined from concentration time data. The analysis was performed in all subjects who received any study medication
and have any available concentration-time data.

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

End point timeframe:

Pre-dose Day 1 to Day 28

| End point values | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 8 | 8 | |
| Units: Hours | | | | |
| median (full range (min-max)) | | | | |
| Day 1 | 5.01 (3 to 12) | 5.05 (4 to 12) | 5 (5 to 6) | |
| Day 28 | 4.5 (0 to 12) | 5 (4 to 6.02) | 4.5 (3 to 6) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Maximum Observed Plasma Concentrations (Cmax) - Part A and C

| End point title | Maximum Observed Plasma Concentrations (Cmax) - Part A and C[3] |
|---|---|

End point description:

Cmax was defined as the peak plasma concentration of a drug after administration, obtained directly from the plasma concentration-time curve. The analysis was performed in all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Pre-dose Day 1 to Day 10

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to evaluate for the specified arm only.

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: nanogram/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Day 1 | 79.376 (± 37.6) | 201.498 (± 21.1) | 349.466 (± 23.2) | 791.317 (± 46.8) |
| Day 10 | 170.778 (± 20.8) | 337.379 (± 20.9) | 705.073 (± 15.4) | 1476.166 (± 17.2) |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 7 |

| | | | | |
|---|---|---|---|---|
| Units: nanogram/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Day 1 | 1155.448 (± 27.1) | 1515.389 (± 27.4) | 793.569 (± 21.2) | 1907.747 (± 38.9) |
| Day 10 | 2466.447 (± 22.1) | 2809.671 (± 25.5) | 1560.122 (± 17.4) | 3377.967 (± 32.8) |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Maximum Observed Plasma Concentrations (Cmax) - Part B

| | |
|---|---|
| End point title | Maximum Observed Plasma Concentrations (Cmax) - Part B |

End point description:

Cmax was defined as the peak plasma concentration of a drug after administration, obtained directly from the plasma concentration-time curve. The analysis was performed in all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Pre-dose Day 1 to Day 28

| End point values | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 8 | 8 | |
| Units: nanogram/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Day 1 | 695.596 (± 9.52) | 770.975 (± 28.2) | 1493.336 (± 24) | |
| Day 28 | 1667.817 (± 30.2) | 1852 (± 33.6) | 3159.181 (± 22.1) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Plasma Concentration 24 Hours Post-Dose (C24) - Part A and C

| | |
|---|---|
| End point title | Plasma Concentration 24 Hours Post-Dose (C24) - Part A and |

End point description:

C24 was defined as the plasma concentration of BMS-955176 at 24 hours post-dose. The analysis was performed in all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Pre-dose Day 1 to Day 10

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to evaluate for the specified arm only.

| **End point values** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: nanogram/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Day 1 | 34.946 (± 28.4) | 79.002 (± 27.2) | 154.5 (± 23.7) | 286.268 (± 15.6) |
| Day 10 | 81.642 (± 23.1) | 138.775 (± 34.1) | 325.934 (± 19.4) | 713.077 (± 21.9) |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 7 |
| Units: nanogram/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Day 1 | 482.349 (± 34.3) | 624.745 (± 24.6) | 339.173 (± 30.1) | 865.867 (± 41) |
| Day 10 | 1150.397 (± 31.5) | 1288.985 (± 26.8) | 779.438 (± 24.6) | 1691.306 (± 29) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Plasma Concentration 24 hours Post-Dose (C24) - Part B

| End point title | Plasma Concentration 24 hours Post-Dose (C24) - Part B |
|---|---|

End point description:

C24 was defined as the plasma concentration of BMS-955176 at 24 hours post-dose. The analysis was performed in all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Pre-dose Day 1 to Day 28

| End point values | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 8 | 8 | |
| Units: nanogram/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Day 1 | 462.312 (± 25) | 520.048 (± 27.7) | 899.364 (± 21.2) | |
| Day 28 | 1099.313 (± 37) | 1163.177 (± 30.9) | 2010.679 (± 19.9) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under The Plasma Concentration - Time Curve Over the Dosing Interval (AUC(TAU)) - Part A and C

| End point title | Area Under The Plasma Concentration - Time Curve Over the Dosing Interval (AUC(TAU)) - Part A and C[5] |
|---|---|

End point description:

AUC(TAU) was defined as the area under the plasma concentration - time curve over the dosing interval. The analysis was performed in all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Pre-dose Day 1 to Day 10

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to evaluate for the specified arm only.

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: nanogram*hour/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Day 1 | 1151.062 (± 32.2) | 2869.626 (± 21.3) | 5132.951 (± 21.5) | 10088.23 (± 23.1) |
| Day 10 | 2720.237 (± 20.7) | 5168.553 (± 23.6) | 11751.82 (± 15.1) | 22984.83 (± 17.2) |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 7 |
| Units: nanogram*hour/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Day 1 | 17057.26 (± 29) | 21872.72 (± 27) | 10936.9 (± 29.9) | 26753.74 (± 35.9) |
| Day 10 | 39341.11 (± 24.2) | 44182.4 (± 27) | 25556.64 (± 20.4) | 53972.71 (± 30.2) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under The Plasma Concentration - Time Curve Over the Dosing Interval (AUC(TAU)) - Part B

| End point title | Area Under The Plasma Concentration - Time Curve Over the Dosing Interval (AUC(TAU)) - Part B |
|---|---|

End point description:

AUC(TAU) was defined as the area under the plasma concentration - time curve over the dosing interval. The analysis was performed in all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Pre-dose Day 1 to Day 28

| End point values | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 8 | 8 | |
| Units: nanogram*hour/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Day 1 | 12147.23 (± 15.2) | 12954.8 (± 26.2) | 24478.35 (± 22.6) | |
| Day 28 | 31406.32 (± 31.7) | 34225.08 (± 30.6) | 59915.72 (± 16.3) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Accumulation index (AI): Part A and C

| End point title | Accumulation index (AI): Part A and C[6] |
|---|---|

End point description:

AI was defined as the ratio of AUC(TAU) at steady-state to AUC(TAU) after the first dose; also calculated for Cmax and C24. AI was derived by non-compartmental methods, using a validated pharmacokinetic (PK) analysis program: KineticaTM 5.0 within eToolbox (version 2.7). The analysis was performed in PK population defined as all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Baseline and Day 10

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to evaluate for the specified arm only.

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Ratio | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Cmax | 2.152 (± 42.9) | 1.674 (± 31.1) | 2.018 (± 39.8) | 1.856 (± 33.6) |
| C24 | 2.336 (± 21.9) | 1.757 (± 35) | 2.11 (± 29.5) | 2.491 (± 24.9) |
| AUC | 2.363 (± 25.9) | 1.801 (± 30.4) | 2.289 (± 39.7) | 2.278 (± 28.2) |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 7 |
| Units: Ratio | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Cmax | 2.135 (± 16.6) | 1.854 (± 22.7) | 1.966 (± 17.2) | 1.771 (± 42.6) |
| C24 | 2.385 (± 25.1) | 2.063 (± 19.3) | 2.298 (± 28.4) | 1.953 (± 42.1) |
| AUC | 2.306 (± 19) | 2.02 (± 19.7) | 2.337 (± 26.1) | 2.017 (± 39) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Apparent total body clearance: Part A and C

| End point title | Apparent total body clearance: Part A and C[7] |
|---|---|

End point description:

Apparent total body clearance was derived by non-compartmental methods, using a validated pharmacokinetic (PK) analysis program: KineticaTM 5.0 within eToolbox (version 2.7). The analysis was performed in PK population defined as all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Baseline (Day 1) to Day 10

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to evaluate for the specified arm only.

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: millilitre(s)/minute | | | | |
| geometric mean (geometric coefficient of variation) | 30.635 (± 18.3) | 32.246 (± 28) | 28.364 (± 15.5) | 29.005 (± 18.8) |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 7 |
| Units: millilitre(s)/minute | | | | |
| geometric mean (geometric coefficient of variation) | 33.892 (± 23.8) | 45.267 (± 34) | 26.086 (± 21.3) | 37.056 (± 33.7) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Degree of Fluctuation (DF): Part A and C

| End point title | Degree of Fluctuation (DF): Part A and C[8] |
|---|---|

End point description:

DF was calculated as the difference between Cmax and Cmin divided by Css-avg. DF was derived by non-compartmental methods, using a validated pharmacokinetic (PK) analysis program: KineticaTM 5.0 within eToolbox (version 2.7). The analysis was performed in PK population defined as all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Baseline (Day 1) to Day 10

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to evaluate for the specified arm only.

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Ratio | | | | |
| geometric mean (geometric coefficient of variation) | 0.766 (± 29.4) | 0.912 (± 15.2) | 0.758 (± 20.2) | 0.78 (± 22.1) |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 7 |
| Units: Ratio | | | | |
| geometric mean (geometric coefficient of variation) | 0.779 (± 28.5) | 0.818 (± 17.1) | 0.723 (± 13.7) | 0.727 (± 24.5) |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Average observed plasma concentration at steady state (Css-avg): Part A and C

| End point title | Average observed plasma concentration at steady state (Css-avg): Part A and C[9] |
|---|---|

End point description:

Css-avg was calculated by the quotient of AUC(TAU) and the dosing interval (24 h). Css-avg was derived by non-compartmental methods, using a validated pharmacokinetic (PK) analysis program: KineticaTM 5.0 within eToolbox (version 2.7). The analysis was performed in PK population defined as all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Baseline (Day 1) to Day 10

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to evaluate for the specified arm only.

| **End point values** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: nanogram/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | 113.326 (± 20.7) | 215.111 (± 23.8) | 489.507 (± 15.1) | 956.222 (± 17.3) |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 7 |
| Units: nanogram/millilitre | | | | |
| geometric mean (geometric coefficient of variation) | 1639.471 (± 24.2) | 1841.413 (± 27) | 1065.435 (± 19.9) | 2256.793 (± 30.2) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Plasma half-life: Part A and C

| End point title | Plasma half-life: Part A and C[10] |
|---|---|

End point description:

Half-life of the terminal log-linear phase, (T-HALF), was calculated as ln2/λ, where λ is the absolute value of the slope of the terminal log-linear phase. T-HALF was derived by non-compartmental methods, using a validated pharmacokinetic (PK) analysis program: KineticaTM 5.0 within eToolbox (version 2.7). The analysis was performed in PK population defined as all subjects who received any study medication and have any available concentration-time data.

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

End point timeframe:

Baseline (Day 1) to Day 10

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to evaluate for the specified arm only.

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: hours | | | | |
| median (full range (min-max)) | 32.134 (25.45 to 46.45) | 31.967 (23.97 to 43.02) | 27.382 (24 to 41.59) | 33.475 (25.79 to 42.39) |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 7 |
| Units: hours | | | | |
| median (full range (min-max)) | 29.171 (24.32 to 38.02) | 34.574 (29.01 to 39.69) | 31.565 (24.39 to 51.64) | 35.278 (26.65 to 38.71) |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Subjects With Clinically Significant Grade 3/4 Laboratory Abnormalities From Baseline

| End point title | Number of Subjects With Clinically Significant Grade 3/4 Laboratory Abnormalities From Baseline |
|---|---|

End point description:

Laboratory abnormalities were determined and graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, version 1.0, December 2004. Neutrophils + bands (absolute): <750/mm^3, Bilirubin (Total) : >2.5*upper limit of normal. The analysis was performed on all subjects who received at least 1 dose of study therapy.

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

End point timeframe:

Day 1 to up to end of the study (Day 42)

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Subjects | | | | |
| Neutrophils (Absolute) | 0 | 0 | 0 | 0 |
| Bilirubin (Total) | 0 | 0 | 0 | 0 |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Subjects | | | | |
| Neutrophils (Absolute) | 0 | 1 | 0 | 0 |
| Bilirubin (Total) | 0 | 0 | 2 | 5 |

| End point values | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: Subjects | | | | |
| Neutrophils (Absolute) | 0 | 1 | 0 | 0 |
| Bilirubin (Total) | 3 | 0 | 0 | 0 |

| End point values | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: Subjects | | | | |
| Neutrophils (Absolute) | 0 | 0 | | |
| Bilirubin (Total) | 0 | 0 | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Subjects With Clinically Significant Changes in Heart Rate

| End point title | Number of Subjects With Clinically Significant Changes in Heart Rate |
|---|---|

End point description:

Heart Rate were measured after the subject had been seated quietly for at least 5 minutes. Criteria used to determine heart rate that are outside of a pre-specified range, where changes from baseline are based on matched postural positions and are calculated as parameter value - baseline parameter value: Value >100 and change from baseline > 30, or Value < 55 and change from baseline < -15. The analysis was performed on all subjects who received at least 1 dose of study therapy.

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

End point timeframe:

Day 1 to up to end of the study (Day 42)

| **End point values** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Subjects | 0 | 0 | 0 | 0 |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Subjects | 0 | 0 | 0 | 0 |

| **End point values** | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: Subjects | 1 | 0 | 0 | 2 |

| **End point values** | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: Subjects | 1 | 0 | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Subjects With Clinically Significant Changes in Electrocardiogram (ECG)

| End point title | Number of Subjects With Clinically Significant Changes in Electrocardiogram (ECG) |
|---|---|

End point description:

Subjects with out of range ECG intervals were summarized. Criteria used to determine ECG results that are outside of a pre-specified range:
PR (msec): Value >200; QRS (msec): Value >120; QT (msec): Value >500 or change from baseline >30; QTcF (msec): Value >450 or change from baseline >30. The analysis was performed on all subjects who received at least 1 dose of study therapy.

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

End point timeframe:

Day 1 to up to end of the study (Day 42)

| End point values | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: millisecond | | | | |
| number (not applicable) | | | | |
| PR > 200 | 1 | 1 | 1 | 0 |
| QRS > 120 | 0 | 0 | 0 | 0 |
| QT > 500 | 0 | 0 | 0 | 0 |
| QTcB > 450 | 0 | 0 | 0 | 0 |
| QTcF > 450 | 0 | 0 | 1 | 0 |

| End point values | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: millisecond | | | | |
| number (not applicable) | | | | |
| PR > 200 | 0 | 2 | 0 | 1 |
| QRS > 120 | 0 | 0 | 1 | 0 |
| QT > 500 | 0 | 0 | 0 | 0 |
| QTcB > 450 | 0 | 0 | 0 | 0 |
| QTcF > 450 | 0 | 0 | 0 | 0 |

| End point values | Part B-Group 7: Atazanavir+Rit | Part B-Group 12: BMS-955176 (80 | Part C-Group 8: BMS-955176 (40 | Part C-Group 13: BMS-955176 (120 |
|---|---|---|---|---|

| | onavir+Tenofovir+Emtricitabine | mg) + Atazanavir | mg) | mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: millisecond | | | | |
| number (not applicable) | | | | |
| PR > 200 | 1 | 1 | 1 | 0 |
| QRS > 120 | 0 | 0 | 0 | 0 |
| QT > 500 | 0 | 0 | 0 | 0 |
| QTcB > 450 | 0 | 0 | 0 | 0 |
| QTcF > 450 | 0 | 0 | 0 | 0 |

| **End point values** | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: millisecond | | | | |
| number (not applicable) | | | | |
| PR > 200 | 0 | 0 | | |
| QRS > 120 | 0 | 0 | | |
| QT > 500 | 0 | 0 | | |
| QTcB > 450 | 0 | 1 | | |
| QTcF > 450 | 0 | 0 | | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Number of Subjects With Abnormal Changes in Physical Examination**

| End point title | Number of Subjects With Abnormal Changes in Physical Examination |
|---|---|

End point description:

Subjects with abnormal changes in physical examination were evaluated. The analysis was performed on all subjects who received at least 1 dose of study therapy.

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

End point timeframe:

Day 1 to up to end of the study (Day 42)

| **End point values** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Subjects | | | | |

| | | | | |
|---|---|---|---|---|
| Height | 0 | 0 | 0 | 0 |
| Weight | 0 | 0 | 0 | 0 |
| Body mass index | 0 | 0 | 0 | 0 |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Subjects | | | | |
| Height | 0 | 0 | 0 | 0 |
| Weight | 0 | 0 | 0 | 0 |
| Body mass index | 0 | 0 | 0 | 0 |

| **End point values** | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: Subjects | | | | |
| Height | 0 | 0 | 0 | 0 |
| Weight | 0 | 0 | 0 | 0 |
| Body mass index | 0 | 0 | 0 | 0 |

| **End point values** | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: Subjects | | | | |
| Height | 0 | 0 | | |
| Weight | 0 | 0 | | |
| Body mass index | 0 | 0 | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Subjects With Clinically Significant Changes in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)

| End point title | Number of Subjects With Clinically Significant Changes in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) |
|---|---|

End point description:

Systolic BP [millimeter of mercury (mmHg)]: value >140 and change from baseline >20, or value <90 and change from baseline <-20; Diastolic BP (mmHg): value >90 and change from baseline >10, or value <55 and change from baseline <-10. The analysis was performed on all subjects who received at least 1 dose of study therapy.

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

End point timeframe:

Day 1 to up to end of the study (Day 42)

| **End point values** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) | Part A-Group 4: BMS-955176 (40 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Subjects | | | | |
| SBP | 0 | 0 | 0 | 0 |
| DBP | 0 | 1 | 1 | 0 |

| **End point values** | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir + Ritonavir |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 8 | 8 | 8 |
| Units: Subjects | | | | |
| SBP | 0 | 0 | 0 | 1 |
| DBP | 0 | 0 | 0 | 1 |

| **End point values** | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 8 | 8 | 7 |
| Units: Subjects | | | | |
| SBP | 0 | 0 | 0 | 0 |
| DBP | 0 | 1 | 1 | 0 |

| End point values | Placebo Clade B | Placebo Clade C | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12 | 4 | | |
| Units: Subjects | | | | |
| SBP | 0 | 0 | | |
| DBP | 1 | 0 | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Day 1 to up to end of the study (Day 42)

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 17.1 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Part A-Group 1: BMS-955176 (5 mg) |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 5 mg BMS-955176 as oral suspension once daily (QD) from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Reporting group title | Part A-Group 2: BMS-955176 (10 mg) |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 10 mg BMS-955176 as oral suspension QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Reporting group title | Part A-Group 3: BMS-955176 (20 mg) |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 20 mg BMS-955176 as oral suspension QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Reporting group title | Part A-Group 4: BMS-955176 (40 mg) |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Reporting group title | Part A-Group 9: BMS-955176 (80 mg) |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 80 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10 under fasting condition. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Reporting group title | Part A-Group 10: BMS-955176 (120 mg) |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 120 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10 under fasting condition. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Reporting group title | Placebo Clade B |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with matching placebo QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| | |
|---|---|
| Reporting group title | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension and 400 mg atazanavir (2*200 mg) capsules, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose.

| | |
|---|---|
| Reporting group title | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir+ Ritonavir |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 40 mg BMS-955176 as oral suspension, 300 mg atazanavir capsules and 100 mg ritonavir tablets, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose.

| | |
|---|---|
| Reporting group title | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine |

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 300 mg tenofovir, 200 mg emtricitabine, 300 mg atazanavir capsules and 100 mg ritonavir tablets, QD from Day 1 to Day 28 with breakfast. Subjects

were evaluated for a total period of 42 days from the day of first dose.

| Reporting group title | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir |
|---|---|

Reporting group description:

Subjects infected with HIV-1 clade B were treated with 80 mg BMS-955176 as oral suspension and 400 mg atazanavir (2*200 mg) capsules, QD from Day 1 to Day 28 with breakfast. Subjects were evaluated for a total period of 42 days from the day of first dose.

| Reporting group title | Part C-Group 8: BMS-955176 (40 mg) |
|---|---|

Reporting group description:

Subjects infected with HIV-1 clade C were treated with 40 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| Reporting group title | Part C-Group 13: BMS-955176 (120 mg) |
|---|---|

Reporting group description:

Subjects infected with HIV-1 clade C were treated with 120 mg BMS-955176 as oral suspension, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| Reporting group title | Placebo Clade C |
|---|---|

Reporting group description:

Subjects infected with HIV-1 clade C were treated with matching placebo, QD from Day 1 to Day 10. Subjects were evaluated for a total period of 24 days from the day of first dose.

| **Serious adverse events** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| **Serious adverse events** | Part A-Group 4: BMS-955176 (40 mg) | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| **Serious adverse events** | Placebo Clade B | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir+ Ritonavir |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| **Serious adverse events** | Part B-Group 7: | Part B-Group 12: | Part C-Group 8: |
|---|---|---|---|

| | Atazanavir+Ritonavir+Tenofovir+Emtricitabine | BMS-955176 (80 mg) + Atazanavir | BMS-955176 (40 mg) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| **Serious adverse events** | Part C-Group 13: BMS-955176 (120 mg) | Placebo Clade C | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

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

| **Non-serious adverse events** | Part A-Group 1: BMS-955176 (5 mg) | Part A-Group 2: BMS-955176 (10 mg) | Part A-Group 3: BMS-955176 (20 mg) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 8 (62.50%) | 5 / 8 (62.50%) | 5 / 8 (62.50%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thrombophlebitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| Nodule | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Catheter site related reaction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhea | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |

| | | | |
|---|---|---|---|
| Abnormal dreams | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all) | 1 | 0 | 3 |
| Sleep disorder | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nightmare | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Agitation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mood swings | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Blood bilirubin unconjugated increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Body temperature increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intraocular pressure increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 2 / 8 (25.00%) | 3 / 8 (37.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Poor quality sleep | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| External ear pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctival haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body sensation in eyes | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Dry mouth | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Faeces hard | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal sounds abnormal | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip swelling | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Jaundice | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Night sweats | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acne | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Myalgia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Candida infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| Gonorrhoea | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased appetite | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Part A-Group 4: BMS-955176 (40 mg) | Part A-Group 9: BMS-955176 (80 mg) | Part A-Group 10: BMS-955176 (120 mg) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 6 / 8 (75.00%) | 8 / 8 (100.00%) | 7 / 8 (87.50%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Thrombophlebitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nodule | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Catheter site related reaction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhea | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Abnormal dreams | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 3 / 8 (37.50%) | 3 / 8 (37.50%) |
| occurrences (all) | 1 | 3 | 3 |
| Sleep disorder | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nightmare | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Agitation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mood swings | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin unconjugated increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Body temperature increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intraocular pressure increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 5 / 8 (62.50%) | 4 / 8 (50.00%) | 5 / 8 (62.50%) |
| occurrences (all) | 7 | 5 | 7 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Poor quality sleep | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| External ear pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye disorders | | | |

| | | | |
|---|---|---|---|
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body sensation in eyes | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Constipation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Faeces hard | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal sounds abnormal | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip swelling | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Jaundice | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Skin and subcutaneous tissue disorders | | | |
| Night sweats | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 1 / 8 (12.50%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 1 | 1 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acne | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Myalgia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 2 / 8 (25.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Candida infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gonorrhoea | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Increased appetite | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Placebo Clade B | Part B-Group 5: BMS-955176 (40 mg) + Atazanavir | Part B-Group 6: BMS-955176 (40 mg) + Atazanavir+ Ritonavir |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 9 / 12 (75.00%) | 8 / 8 (100.00%) | 8 / 8 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |

| | | | |
|---|---|---|---|
| Anogenital warts | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thrombophlebitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nodule | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Catheter site related reaction | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensation of foreign body | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhea | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | | | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Cough | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psychiatric disorders | | | |
| Abnormal dreams | | | |
| subjects affected / exposed | 3 / 12 (25.00%) | 3 / 8 (37.50%) | 3 / 8 (37.50%) |
| occurrences (all) | 3 | 3 | 3 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nightmare | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 2 / 8 (25.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Agitation | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mood swings | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Investigations | | | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 6 / 8 (75.00%) | 8 / 8 (100.00%) |
| occurrences (all) | 0 | 6 | 8 |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin unconjugated increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Body temperature increased | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intraocular pressure increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 5 / 12 (41.67%) | 5 / 8 (62.50%) | 3 / 8 (37.50%) |
| occurrences (all) | 7 | 10 | 4 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Poor quality sleep | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysaesthesia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 8 (12.50%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Eosinophilia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| External ear pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 8 (12.50%) | 3 / 8 (37.50%) |
| occurrences (all) | 0 | 1 | 3 |
| Eye pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Foreign body sensation in eyes | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 3 / 8 (37.50%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 5 | 3 |
| Constipation | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 8 (12.50%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 1 | 1 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal pain upper | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Faeces hard | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal sounds abnormal | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lip swelling | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |

| | | | |
|---|---|---|---|
| Jaundice | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 2 / 8 (25.00%) | 4 / 8 (50.00%) |
| occurrences (all) | 0 | 2 | 4 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Night sweats | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 2 / 8 (25.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 2 | 2 |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Acne | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 8 (12.50%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eczema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Myalgia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |

| | | | |
|---|---|---|---|
| Nasopharyngitis | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Candida infection | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gonorrhoea | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased appetite | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Part B-Group 7: Atazanavir+Ritonavir+Tenofovir+Emtricitabine | Part B-Group 12: BMS-955176 (80 mg) + Atazanavir | Part C-Group 8: BMS-955176 (40 mg) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 4 / 4 (100.00%) | 6 / 8 (75.00%) | 7 / 8 (87.50%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thrombophlebitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nodule | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Malaise | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Catheter site related reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhea | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Abnormal dreams | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 3 / 8 (37.50%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 3 | 2 |
| Sleep disorder | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nightmare | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| Agitation | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mood swings | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 4 / 4 (100.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin unconjugated increased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Body temperature increased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intraocular pressure increased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 2 / 4 (50.00%) | 4 / 8 (50.00%) | 4 / 8 (50.00%) |
| occurrences (all) | 2 | 5 | 4 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Poor quality sleep | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 2 / 8 (25.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Dysaesthesia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 8 (12.50%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| External ear pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body sensation in eyes | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|---|---|
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 4 (50.00%) | 3 / 8 (37.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 3 | 10 | 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 8 (12.50%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Nausea | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Faeces hard | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Gastrointestinal sounds abnormal | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip swelling | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Jaundice | | | |
| subjects affected / exposed | 3 / 4 (75.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 3 / 8 (37.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Night sweats | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 2 / 4 (50.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acne | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis allergic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Myalgia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Back pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 2 / 4 (50.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Candida infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gonorrhoea | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 8 (12.50%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Sinusitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Increased appetite | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 8 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| **Non-serious adverse events** | Part C-Group 13: BMS-955176 (120 mg) | Placebo Clade C | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 6 / 7 (85.71%) | 3 / 4 (75.00%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Thrombophlebitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 4 (25.00%) | |
| occurrences (all) | 0 | 1 | |
| Nodule | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Malaise | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Chills | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Catheter site related reaction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Reproductive system and breast disorders | | | |
| Dysmenorrhea | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cough | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Psychiatric disorders | | | |
| Abnormal dreams | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nightmare | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Agitation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Mood swings | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Investigations | | | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood bilirubin unconjugated increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Body temperature increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Intraocular pressure increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 3 / 4 (75.00%) | |
| occurrences (all) | 3 | 4 | |
| Dizziness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Poor quality sleep | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Eosinophilia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ear and labyrinth disorders | | | |
| External ear pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Eye disorders | | | |
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Eye pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dry eye | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Eye irritation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Foreign body sensation in eyes | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 4 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Constipation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 4 (25.00%) | |
| occurrences (all) | 0 | 1 | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nausea | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Toothache | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | | |
|---|---|---|---|
| Faeces hard | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Flatulence | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gastrointestinal sounds abnormal | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 4 (25.00%) | |
| occurrences (all) | 0 | 1 | |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lip swelling | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hepatobiliary disorders | | | |
| Jaundice | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Night sweats | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pruritus | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 4 (25.00%) | |
| occurrences (all) | 0 | 1 | |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Acne | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urticaria | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rash | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dry skin | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Eczema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Erythema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Rash papular | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 4 (25.00%) | |
| occurrences (all) | 0 | 1 | |
| Musculoskeletal and connective tissue disorders | | | |
| Myalgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Back pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 4 (25.00%) | |
| occurrences (all) | 0 | 1 | |
| Bone pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Groin pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Neck pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Candida infection | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Folliculitis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gonorrhoea | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | | |
|---|---|---|---|
| Lower respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 0 / 7 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0 | |
| Pulpitis dental<br>subjects affected / exposed<br>occurrences (all) | 0 / 7 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0 | |
| Sinusitis<br>subjects affected / exposed<br>occurrences (all) | 0 / 7 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0 | |
| Metabolism and nutrition disorders<br>Decreased appetite<br>subjects affected / exposed<br>occurrences (all) | 0 / 7 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0 | |
| Increased appetite<br>subjects affected / exposed<br>occurrences (all) | 0 / 7 (0.00%)<br>0 | 0 / 4 (0.00%)<br>0 | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 28 February 2013 | Revised criteria and timing of subject enrollment for Part B and C; fixed study dose for Part C; clarified blinding requirement in Part A; replaced 300 mg tenofovir tablet, QD, 200 mg emtricitabine capsule, QD with Truvada®; revised method of enrollment and randomisation, and method of emergency unblinding; and moved pregnancy test from Day 15 to Day 14; modified laboratory tests; revised the languages for the interim analysis; and include other study clarifications. |
| 05 September 2013 | The primary purpose of this amendment is to update contraception requirements for male subjects and women of childbearing potential who will enroll in the study. |
| 24 December 2013 | Included rationale for new Treatment Groups. Added a secondary objective and two exploratory objectives. Updated study design and duration. |
| 27 February 2014 | The primary purpose of this amendment is to add a troponin I test in laboratory test assessments and to clarify sample collection for lipid profile. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported