



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
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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

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)
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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)
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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
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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
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
Completed	8	8	8

Number of subjects in period 1 ^[1]	Placebo Clade B
	Started
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
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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
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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
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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
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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
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)
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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 Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	39.5 ± 8.09	36.3 ± 11.23	38 ± 9.49
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	8

Reporting group values	Placebo Clade B	Total	
Number of subjects	12	60	
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	36.3 ± 7.12	-	
Gender categorical 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)
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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
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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 Log ₁₀ HIV-1 Ribonucleic Acid (RNA) Levels from Baseline to Day 11 ^[1]
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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
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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]
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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
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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
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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
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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+Rit onavir+Tenof ovir+Emtricitab ine	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)
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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
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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)
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)

	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)
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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
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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) +
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)

			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+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
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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
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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
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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
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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
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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
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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]
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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
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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 C

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
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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
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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
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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]
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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
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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]
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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 C_{max} and C₂₄. AI was derived by non-compartmental methods, using a validated pharmacokinetic (PK) analysis program: Kinetica™ 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
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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)				
C _{max}	2.152 (± 42.9)	1.674 (± 31.1)	2.018 (± 39.8)	1.856 (± 33.6)
C ₂₄	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)				
C _{max}	2.135 (± 16.6)	1.854 (± 22.7)	1.966 (± 17.2)	1.771 (± 42.6)
C ₂₄	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: Kinetica™ 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 C_{ss}-avg. DF was derived by non-compartmental methods, using a validated pharmacokinetic (PK) analysis program: Kinetica™ 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 (C_{ss}-avg): Part A and C

End point title Average observed plasma concentration at steady state (C_{ss}-avg): Part A and C^[9]

End point description:

C_{ss}-avg was calculated by the quotient of AUC(TAU) and the dosing interval (24 h). C_{ss}-avg was derived by non-compartmental methods, using a validated pharmacokinetic (PK) analysis program: Kinetica™ 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 (\pm 20.7)	215.111 (\pm 23.8)	489.507 (\pm 15.1)	956.222 (\pm 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 (\pm 24.2)	1841.413 (\pm 27)	1065.435 (\pm 19.9)	2256.793 (\pm 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 $\ln 2/\lambda$, 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: Kinetica™ 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
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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/mm³, 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
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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+Rit onavir+Tenof ovir+Emtricitab ine	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
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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)
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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
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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
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

	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
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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
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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)
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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
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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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.1
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Reporting groups

Reporting group title	Part A-Group 1: BMS-955176 (5 mg)
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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)
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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)
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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)
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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)
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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)
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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
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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
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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
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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
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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
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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)
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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)
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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
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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:
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	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 occurrences (all)	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0	3 / 8 (37.50%) 3
Sleep disorder subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Nightmare subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Agitation subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Mood swings subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Investigations			
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1	1 / 8 (12.50%) 1
Blood bilirubin unconjugated increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Intraocular pressure increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Neutrophil count decreased			

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

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

subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Intraocular pressure increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	5 / 8 (62.50%) 7	4 / 8 (50.00%) 5	5 / 8 (62.50%) 7
Dizziness subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Poor quality sleep subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Dysaesthesia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Blood and lymphatic system disorders			
Neutropenia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Eosinophilia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Ear and labyrinth disorders			
External ear pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 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 occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Thrombophlebitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Nodule subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Asthenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Catheter site related reaction subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Sensation of foreign body subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 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 occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Blood bilirubin unconjugated increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Intraocular pressure increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	5 / 12 (41.67%) 7	5 / 8 (62.50%) 10	3 / 8 (37.50%) 4
Dizziness subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Poor quality sleep subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Dysaesthesia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Blood and lymphatic system disorders			
Neutropenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	1 / 8 (12.50%) 1
Eosinophilia			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Ear and labyrinth disorders External ear pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Eye disorders Ocular icterus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	3 / 8 (37.50%) 3
Eye pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Dry eye subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Eye irritation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Foreign body sensation in eyes subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	3 / 8 (37.50%) 5	2 / 8 (25.00%) 3
Constipation subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	1 / 8 (12.50%) 1	1 / 8 (12.50%) 1
Abdominal pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 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 occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Rash papular subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Myalgia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Bone pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Musculoskeletal stiffness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 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 occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1	0 / 8 (0.00%) 0
Sensation of foreign body subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhea subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Epistaxis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Psychiatric disorders Abnormal dreams subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	3 / 8 (37.50%) 3	2 / 8 (25.00%) 2
Sleep disorder subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Nightmare subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Agitation subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Mood swings			

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

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1	2 / 8 (25.00%) 2
Eosinophilia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Ear and labyrinth disorders External ear pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Eye disorders Ocular icterus subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	1 / 8 (12.50%) 1
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Dry eye subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Eye irritation subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Foreign body sensation in eyes subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 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 occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Haemorrhoids thrombosed subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Lip swelling subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Hepatobiliary disorders			
Jaundice subjects affected / exposed occurrences (all)	3 / 4 (75.00%) 3	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	3 / 8 (37.50%) 3	0 / 8 (0.00%) 0
Skin and subcutaneous tissue disorders			
Night sweats subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 2	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Dermatitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Acne subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Urticaria subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 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 occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 0
Increased appetite subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 8 (0.00%) 0	0 / 8 (0.00%) 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 occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Thrombophlebitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 4 (25.00%) 1	
Nodule subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Malaise subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 4 (0.00%) 0	
Chills			

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

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

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Poor quality sleep subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Dysaesthesia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Paraesthesia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Eosinophilia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 4 (0.00%) 0	
Ear and labyrinth disorders External ear pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Eye disorders Ocular icterus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Eye pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Dry eye subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 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 subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Pulpitis dental subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Sinusitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	
Increased appetite subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 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