Clinical trial results:
A Phase IIb Randomized, Controlled, Partially Blinded Clinical Trial to Investigate Safety, Efficacy and Dose-response of BMS-986001 in Treatment-naive HIV-1-infected Subjects, Followed by an Open-label Period on the Recommended Dose.

Summary

EudraCT number	2011-003329-89
Trial protocol	HU ES DE PL
Global end of trial date	11 July 2014

Results information

Result version number	v1 (current)
This version publication date	24 November 2016
First version publication date	24 November 2016

Trial information

Trial identification

Sponsor protocol code	AI467-003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01489046
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chausée de la Hulpe 185,, Brussels, Belgium, 1170
Public contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb International Corporation, clinical.trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb International Corporation, 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	11 July 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 July 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objectives of this trial were to assess the efficacy of three doses of BMS-986001 by determining the proportion of subjects with plasma HIV-1 RNA < 50 c/mL as measured by PCR analyses at Week 24 and to assess the safety of three doses of BMS-986001 in treatment-naive HIV-1 infected subjects as measured by numbers of subjects with SAEs and numbers of subjects with AEs leading to discontinuations through Week 24.

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:

Subjects in all 4 treatment groups received once daily (QD) efavirenz (EFV) 600 mg and lamivudine (3TC) 300 mg in addition to their assigned blinded study therapy. EFV and 3TC were open label throughout the study. All doses were taken daily on an empty stomach at bedtime.

Evidence for comparator:

Per current HIV guidelines an early start of antiretroviral (ARV) therapy is recommended while subjects have higher CD4+ T-cell counts. Tenofovir disoproxil fumarate (TDF), a nucleoside/nucleotide reverse transcriptase inhibitor (NRTI), is a widely used first-line regimen, but there are concerns about potential long-term toxicities.

Actual start date of recruitment	21 March 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 17
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Australia: 10
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Chile: 22
Country: Number of subjects enrolled	Colombia: 16
Country: Number of subjects enrolled	Mexico: 9
Country: Number of subjects enrolled	Peru: 83
Country: Number of subjects enrolled	South Africa: 385
Country: Number of subjects enrolled	Thailand: 124
Country: Number of subjects enrolled	United States: 84

Worldwide total number of subjects	757
EEA total number of subjects	19

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)	756
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 41 sites in 12 countries.

Pre-assignment

Screening details:

757 subjects enrolled, 301 subjects were randomized. Reasons not randomized: 14 withdrew consent, 4 lost to follow-up, 1 administrative reason by sponsor, 414 no longer met study criteria, 1 poor/non-compliance, 22 other. 297 subjects treated. Reasons not treated: 2 no longer met study criteria, 2 withdrew consent.

Period 1

Period 1 title	Treatment Stage 1 (up to Week 96)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Blinding implementation details:

Blinding was conducted up to the Week 48 analysis. After Week 48, the study was un-blinded for the rest of the trial.

Arms

Are arms mutually exclusive?	Yes
Arm title	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Arm description:

In Stage 1, subjects were administered a QD dose of 100 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 100 mg active dose of BMS-986001 and matched-placebo. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects switched to an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1.

Arm type	Experimental
Investigational medicinal product name	BMS-986001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Up to the Week 48 analysis, subjects were administered a QD dose of 100 mg BMS-986001 under fasted conditions at bedtime. After the Week 48 analysis, subjects were switched to the optimal QD dose of 400 mg BMS-986001 under fasted conditions at bedtime. The therapy was administered as a two piece, gray, opaque, size #0, hard gelatin capsule filled with white to off-white powder.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of placebo matching to BMS-986001 under fasted conditions at bedtime. The therapy was administered as a two piece, gray, opaque, size #0, hard gelatin capsule filled with white to off-white powder.

Investigational medicinal product name	EFV
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 600 mg EFV under fasted conditions at bedtime. The therapy was administered as a yellow capsular shaped film-coated tablet. Upon sponsor request EFV could also be administered as three 200mg tablets.

Investigational medicinal product name	3TC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg 3TC under fasted conditions at bedtime. The therapy was administered as a grey diamond-shaped film-coated tablet.

Arm title	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Arm description:

In Stage 1, subjects were administered a QD dose of 200 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 200 mg active dose of BMS-986001 and matched-placebo. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects switched to an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1.

Arm type	Experimental
Investigational medicinal product name	BMS-986001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Up to the Week 48 analysis, subjects were administered a QD dose of 200 mg BMS-986001 under fasted conditions at bedtime. After the Week 48 analysis, subjects were switched to the optimal QD dose of 400 mg BMS-986001 under fasted conditions at bedtime. The therapy was administered as a two piece, gray, opaque, size #0, hard gelatin capsule filled with white to off-white powder.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of placebo matching to BMS-986001 under fasted conditions at bedtime. The therapy was administered as a two piece, gray, opaque, size #0, hard gelatin capsule filled with white to off-white powder.

Investigational medicinal product name	EFV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 600 mg EFV under fasted conditions at bedtime. The therapy was administered as a yellow capsular shaped film-coated tablet. Upon sponsor request EFV could also be administered as three 200mg tablets.

Investigational medicinal product name	3TC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg 3TC under fasted conditions at bedtime. The therapy was administered as a grey diamond-shaped film-coated tablet.

Arm title	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Arm description:

In Stage 1, subjects were administered a QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 400 mg active dose of BMS-986001. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects continued the optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1.

Arm type	Experimental
Investigational medicinal product name	BMS-986001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Up to the Week 48 analysis, subjects were administered a QD dose of 400 mg BMS-986001 under fasted conditions at bedtime. After the Week 48 analysis, subjects continued at the optimal QD dose of 400 mg BMS-986001 under fasted conditions at bedtime. The therapy was administered as a two piece, gray, opaque, size #0, hard gelatin capsule filled with white to off-white powder.

Investigational medicinal product name	EFV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 600 mg EFV under fasted conditions at bedtime. The therapy was administered as a yellow capsular shaped film-coated tablet. Upon sponsor request EFV could also be administered as three 200mg tablets.

Investigational medicinal product name	3TC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg 3TC under fasted conditions at bedtime. The therapy was administered as a grey diamond-shaped film-coated tablet.

Arm title	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Arm description:

In Stage 1, subjects were administered a QD dose of 300 mg TDF, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. Dosing was open-label for TDF, EFV and 3TC.

Arm type	Active comparator
Investigational medicinal product name	TDF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg TDF under fasted conditions at bedtime. The therapy was administered as an almond-shaped light blue film-coated tablet.

Investigational medicinal product name	EFV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 600 mg EFV under fasted conditions at bedtime. The therapy was administered as a yellow capsular shaped film-coated tablet. Upon sponsor request EFV could also be administered as three 200mg tablets.

Investigational medicinal product name	3TC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg 3TC under fasted conditions at bedtime. The therapy was administered as a grey diamond-shaped film-coated tablet.

Number of subjects in period 1[1]	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Started	65	67	66
Completed	34	38	40
Not completed	31	29	26
Consent withdrawn by subject	1	2	-
Poor/Non-Compliance	1	-	1
Adverse event, non-fatal	1	5	3
Other	-	-	-
Subject No Longer Met Study Criteria	7	6	2
Pregnancy	1	-	-
Subject Request to Discontinue Study Treatment	-	-	1
Lost to follow-up	6	3	3
Administrative Reason by Sponsor	12	13	15
Lack of efficacy	2	-	1

Number of subjects in period 1[1]	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Started	99
Completed	44
Not completed	55
Consent withdrawn by subject	4
Poor/Non-Compliance	2
Adverse event, non-fatal	4
Other	1

Subject No Longer Met Study Criteria	-
Pregnancy	2
Subject Request to Discontinue Study Treatment	2
Lost to follow-up	10
Administrative Reason by Sponsor	29
Lack of efficacy	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial as out of 757 subjects who were enrolled, 297 subjects were treated in the study.

Period 2

Period 2 title	Treatment Stage 2 (post Week 96)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Arm description:

In Stage 2, subjects continued the un-blinded, post-Week 48 treatment regimen from Stage 1 which consisted of an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. During Stage 1 (prior to Week 48), the subjects in this group were originally administered a blinded QD dose of 100 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime.

Arm type	Experimental
Investigational medicinal product name	BMS-986001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

In Stage 2, subjects continued the post-Week 48 regimen where they were administered the optimal QD dose of 400 mg BMS-986001 under fasted conditions at bedtime. Prior to Week 48, subjects were originally administered a QD dose of 100 mg BMS-986001 under fasted conditions at bedtime. The therapy was administered as a two piece, gray, opaque, size #0, hard gelatin capsule filled with white to off-white powder.

Investigational medicinal product name	EFV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 600 mg EFV under fasted conditions at bedtime. The therapy was administered as a yellow capsular shaped film-coated tablet. Upon sponsor request EFV could also be administered as three 200mg tablets.

Investigational medicinal product name	3TC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet

Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg 3TC under fasted conditions at bedtime. The therapy was administered as a grey diamond-shaped film-coated tablet.

Arm title	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Arm description:

In Stage 2, subjects continued the un-blinded, post-Week 48 treatment regimen from Stage 1 which consisted of an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. During Stage 1 (prior to Week 48), the subjects in this group were originally administered a blinded QD dose of 200 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime.

Arm type	Experimental
Investigational medicinal product name	BMS-986001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

In Stage 2, subjects continued the post-Week 48 regimen where they were administered the optimal QD dose of 400 mg BMS-986001 under fasted conditions at bedtime. Prior to Week 48, subjects were originally administered a QD dose of 200 mg BMS-986001 under fasted conditions at bedtime. The therapy was administered as a two piece, gray, opaque, size #0, hard gelatin capsule filled with white to off-white powder.

Investigational medicinal product name	EFV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 600 mg EFV under fasted conditions at bedtime. The therapy was administered as a yellow capsular shaped film-coated tablet. Upon sponsor request EFV could also be administered as three 200mg tablets.

Investigational medicinal product name	3TC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg 3TC under fasted conditions at bedtime. The therapy was administered as a grey diamond-shaped film-coated tablet.

Arm title	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Arm description:

In Stage 2, subjects continued the un-blinded, post-Week 48 treatment regimen from Stage 1 which consisted of an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. During Stage 1 (prior to Week 48), the subjects in this group were originally administered a blinded QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime.

Arm type	Experimental
Investigational medicinal product name	BMS-986001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Up to the Week 48 analysis, subjects were administered a QD dose of 400 mg BMS-986001 under fasted conditions at bedtime. After the Week 48 analysis, subjects continued the optimal QD dose of 400 mg BMS-986001 under fasted conditions at bedtime. The therapy was administered as a two piece, gray, opaque, size #0, hard gelatin capsule filled with white to off-white powder.

Investigational medicinal product name	EFV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 600 mg EFV under fasted conditions at bedtime. The therapy was administered as a yellow capsular shaped film-coated tablet. Upon sponsor request EFV could also be administered as three 200mg tablets.

Investigational medicinal product name	3TC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg 3TC under fasted conditions at bedtime. The therapy was administered as a grey diamond-shaped film-coated tablet.

Arm title	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Arm description:

In Stage 2, subjects continued the treatment regimen from Stage 1 which consisted of a QD dose of 300 mg TDF, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. Dosing was open-label for TDF, EFV and 3TC.

Arm type	Active comparator
Investigational medicinal product name	TDF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg TDF under fasted conditions at bedtime. The therapy was administered as an almond-shaped light blue film-coated tablet.

Investigational medicinal product name	EFV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 600 mg EFV under fasted conditions at bedtime. The therapy was administered as a yellow capsular shaped film-coated tablet. Upon sponsor request EFV could also be administered as three 200mg tablets.

Investigational medicinal product name	3TC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were administered a QD dose of 300 mg 3TC under fasted conditions at bedtime. The therapy was administered as a grey diamond-shaped film-coated tablet.

Number of subjects in period 2[2]	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Started	20	25	23
Completed	0	0	0
Not completed	20	25	23
Lost to follow-up	1	-	-
Administrative Reason by Sponsor	19	25	23

Number of subjects in period 2[2]	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Started	22
Completed	0
Not completed	22
Lost to follow-up	-
Administrative Reason by Sponsor	22

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: The number of subjects reported to start the period is not consistent with the number completing the preceding period as out of 156 subjects who completed the previous period (Stage 1), only 92 subjects opted to continue to to this period (Stage 2) in the study.

Baseline characteristics

Reporting groups	
Reporting group title	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Reporting group description:	
In Stage 1, subjects were administered a QD dose of 100 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 100 mg active dose of BMS-986001 and matched-placebo. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects switched to an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1.	
Reporting group title	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Reporting group description:	
In Stage 1, subjects were administered a QD dose of 200 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 200 mg active dose of BMS-986001 and matched-placebo. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects switched to an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1.	
Reporting group title	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Reporting group description:	
In Stage 1, subjects were administered a QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 400 mg active dose of BMS-986001. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects continued the optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1.	
Reporting group title	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Reporting group description:	
In Stage 1, subjects were administered a QD dose of 300 mg TDF, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. Dosing was open-label for TDF, EFV and 3TC.	

Reporting group values	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Number of subjects	65	67	66
Age categorical Units: Subjects			
Adults (18 to 64 years)	65	67	66
Age continuous Units: years			
arithmetic mean	32.1	32.7	34.5
full range (min-max)	18 to 64	18 to 53	19 to 57
Gender categorical Units: Subjects			
Female	22	25	25
Male	43	42	41
Race			
"Other" included Cape colored, South American, multiracial, and mixed			
Units: Subjects			
White	11	10	7
Black/African American	31	32	35
Asian	15	15	14

Other	8	10	10
HIV-1 RNA Categories Units: Subjects			
< 30,000 c/mL	37	37	34
30,000 c/mL to < 100,000 c/mL	17	18	20
100,000 c/mL to < 500,000 c/mL	10	10	11
≥ 500,000 c/mL	1	2	1
CD4+ T-cell Categories Units: Subjects			
100 to < 200 cells/uL	6	3	4
200 to < 350 cells/uL	40	39	36
350 to < 500 cells/uL	12	17	20
≥ 500 cells/uL	7	8	6
HIV-1 Subtype Units: Subjects			
Type AE	14	13	8
Type B	28	22	24
Type BF	0	0	1
Type C	22	30	29
Complex	1	2	4
Plasma HIV-1 RNA Units: (log 10 c/mL			
median	4.34	4.43	4.455
standard deviation	± 0.683	± 0.6398	± 0.6361
CD4+ T-Cell Counts Units: cells/UL			
median	290	325	330
standard deviation	± 130.55	± 125.36	± 138.08

Reporting group values	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD	Total	
Number of subjects	99	297	
Age categorical Units: Subjects			
Adults (18 to 64 years)	99	297	
Age continuous Units: years			
arithmetic mean	31.8		
full range (min-max)	18 to 61	-	
Gender categorical Units: Subjects			
Female	29	101	
Male	70	196	
Race			
"Other" included Cape colored, South American, multiracial, and mixed			
Units: Subjects			
White	15	43	
Black/African American	40	138	
Asian	27	71	
Other	17	45	
HIV-1 RNA Categories			

Units: Subjects			
< 30,000 c/mL	61	169	
30,000 c/mL to < 100,000 c/mL	21	76	
100,000 c/mL to < 500,000 c/mL	17	48	
≥ 500,000 c/mL	0	4	
CD4+ T-cell Categories Units: Subjects			
100 to < 200 cells/uL	12	25	
200 to < 350 cells/uL	59	174	
350 to < 500 cells/uL	19	68	
≥ 500 cells/uL	9	30	
HIV-1 Subtype Units: Subjects			
Type AE	25	60	
Type B	36	110	
Type BF	1	2	
Type C	33	114	
Complex	4	11	
Plasma HIV-1 RNA Units: (log 10 c/mL			
median	4.38		
standard deviation	± 0.61	-	
CD4+ T-Cell Counts Units: cells/UL			
median	301		
standard deviation	± 141.79	-	

End points

End points reporting groups

Reporting group title	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 1, subjects were administered a QD dose of 100 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 100 mg active dose of BMS-986001 and matched-placebo. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects switched to an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1.

Reporting group title	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 1, subjects were administered a QD dose of 200 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 200 mg active dose of BMS-986001 and matched-placebo. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects switched to an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1.

Reporting group title	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 1, subjects were administered a QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 400 mg active dose of BMS-986001. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects continued the optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1.

Reporting group title	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 1, subjects were administered a QD dose of 300 mg TDF, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. Dosing was open-label for TDF, EFV and 3TC.

Reporting group title	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 2, subjects continued the un-blinded, post-Week 48 treatment regimen from Stage 1 which consisted of an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. During Stage 1 (prior to Week 48), the subjects in this group were originally administered a blinded QD dose of 100 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime.

Reporting group title	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 2, subjects continued the un-blinded, post-Week 48 treatment regimen from Stage 1 which consisted of an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. During Stage 1 (prior to Week 48), the subjects in this group were originally administered a blinded QD dose of 200 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime.

Reporting group title	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 2, subjects continued the un-blinded, post-Week 48 treatment regimen from Stage 1 which consisted of an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. During Stage 1 (prior to Week 48), the subjects in this group were originally administered a blinded QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime.

Reporting group title	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 2, subjects continued the treatment regimen from Stage 1 which consisted of a QD dose of 300 mg TDF, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. Dosing was open-label for TDF, EFV and 3TC.

Primary: Proportion of subjects with HIV-1 RNA < 50 c/mL at Week 24

End point title	Proportion of subjects with HIV-1 RNA < 50 c/mL at Week 24[1]

End point description:

The proportion of subjects with plasma human immunodeficiency virus 1 (HIV-1) ribonucleic acid (RNA) levels less than 50 copies per milliliter (c/ml) consisted of the modified intent to treat (mITT) population and was defined as a percentage where the number of subjects with plasma HIV-1 RNA < 50 c/ml at Week 24 was divided by the total number of treated subjects. Treated subjects were randomized subjects who received at least 1 dose of study therapy. Response was assessed with the snapshot algorithm, which used the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.

End point type	Primary

End point timeframe:

Week 24

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 summary statistics were planned for this outcome measure.

End point values	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	67	66	99
Units: proportion of subjects				
number (confidence interval 95%)	87.7 (77.2 to 94.5)	80.6 (69.1 to 89.2)	93.9 (85.2 to 98.3)	87.9 (79.8 to 93.6)

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with SAEs, AEs leading to discontinuation, Death through Week 24

End point title	Number of Subjects with SAEs, AEs leading to discontinuation, Death through Week 24[2]

End point description:

An adverse event (AE) was defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation subject administered an investigational (medicinal) product and that does not necessarily have a causal relationship with this treatment. A serious adverse event (SAE) was defined as 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. Death was a fatal event leading to permanent cessations of all vital functions of the body. The analysis was performed in the safety set, defined as all treated subjects. Treated subjects were randomized subjects who received at least 1 dose of study therapy.

End point type	Primary

End point timeframe:

Day 1 to Week 24

Notes:

[2] - 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 summary statistics were planned for this outcome measure.

End point values	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	67	66	99
Units: subjects				
SAEs	4	4	4	9
AEs Leading to Discontinuation	0	5	0	3
Death	0	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects with HIV-1 RNA < 50 c/mL through Weeks 48 and 96

End point title	Proportion of subjects with HIV-1 RNA < 50 c/mL through Weeks 48 and 96

End point description:

The proportion of subjects with plasma HIV-1 RNA levels less than 50 c/ml consisted of the mITT population and was defined as a percentage where the number of subjects with plasma HIV-1 RNA < 50 c/ml at Week 48 or 96 was divided by the total number of treated subjects. Treated subjects were randomized subjects who received at least 1 dose of study therapy. Response was assessed with the snapshot algorithm, which used the last plasma HIV-1 RNA value in the predefined visit window to classify a subject's response status.

End point type	Secondary

End point timeframe:

Day 1 to Week 96

End point values	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	67	66	99
Units: proportion of subjects				
number (confidence interval 95%)				
Week 48	75.4 (63.1 to 85.2)	80.6 (69.1 to 89.2)	89.4 (79.4 to 95.6)	81.8 (72.8 to 88.9)
Week 96	46.2 (33.7 to 59)	52.2 (39.7 to 64.6)	59.1 (46.3 to 71)	42.4 (32.5 to 52.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with SAEs, AEs leading to discontinuation, Death through Week 96

End point title	Number of Subjects with SAEs, AEs leading to discontinuation, Death through Week 96

End point description:

AE was defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation subject administered an investigational (medicinal) product and that does not necessarily have a causal relationship with this treatment. A SAE was defined as 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. Death was a fatal event leading to permanent cessations of all vital functions of the body. The analysis was performed in the safety set, defined as all treated subjects. Treated subjects were randomized subjects who received at least 1 dose of study therapy.

End point type	Secondary

End point timeframe:

Day 1 to Week 96

End point values	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	65	65	99
Units: subjects				
SAE, Week 96	7	7	9	11
AEs leading to discontinuation, Week 96	1	5	3	4
Death, Week 96	0	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in Cluster of Differentiation 4 Positive (CD4+) T-cell count through Weeks 24, 48, and 96

End point title	Mean Change from Baseline in Cluster of Differentiation 4 Positive (CD4+) T-cell count through Weeks 24, 48, and 96

End point description:

Changes from baseline in CD4+ T-cell counts were determined as cells per microliter (cells/ul). The analysis was performed in the observed set of the treated population, defined as subjects with CD4 < 50

c/mL at each measured week divided by the total number of treated subjects with CD4 at each measured week. Treated subjects were randomized subjects who received at least 1 dose of study therapy. Here n = number of subjects analysed and signifies evaluable subjects for this end point.

End point type	Secondary

End point timeframe:

Day 1 to Week 96

End point values	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	54	63	89
Units: cells/ul				
arithmetic mean (standard error)				
Week 24 (n=59, 54, 63, 89)	171.4 (± 16.379)	139.6 (± 16.9)	122.7 (± 14.243)	133.1 (± 12.149)
Week 48 (n=51, 52, 57, 82)	189.2 (± 20.072)	155.3 (± 17.591)	155.4 (± 15.772)	179.8 (± 19.377)
Week 96 (n=37, 43, 45, 56)	264.1 (± 27.36)	255.6 (± 27.765)	199.2 (± 19.598)	215.7 (± 24.671)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with virologic failure who exhibited genotypic substitutions in viral RNA through Weeks 24, 48, and 96

End point title	Number of subjects with virologic failure who exhibited genotypic substitutions in viral RNA through Weeks 24, 48, and 96

End point description:

Virologic failure was defined as confirmed HIV-1 RNA >= 400 copies/mL after achieving viral suppression (HIV-1 RNA < 50 copies/mL) or discontinuation from study prior to achieving viral suppression after Week 8 with the last plasma HIV-1 RNA >= 400 copies/mL. The analysis was performed on all treated subjects with resistance profiles up to the specified week analysis. Here n = number of subjects analysed and signifies evaluable subjects for this end point.

End point type	Secondary

End point timeframe:

Day 1 to Week 96

End point values	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	7	3	6
Units: subjects				
Week 24 (n=6, 5, 1, 2)	4	2	1	0
Week 48 (n=10, 6, 2, 4)	5	2	1	0
Week 96 (n=12, 7, 3, 6)	5	3	2	1

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Day 1 up to 30 days after the last dose of the study drug (approximately 28 months)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 1, subjects were administered a QD dose of 100 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 100 mg active dose of BMS-986001 and matched-placebo. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects switched to an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1 and the completion of stage 2.

Reporting group title	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 1, subjects were administered a QD dose of 200 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 200 mg active dose of BMS-986001 and matched-placebo. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects switched to an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1. After the Week 48 analysis, the study became un-blinded and subjects switched to an optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1 and the completion of stage 2.

Reporting group title	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 1, subjects were administered a QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. While blinded, subjects took 4 capsules, 1 from each of 4 bottles that were a blinded combination of 400 mg active dose of BMS-986001. Dosing was open-label for EFV and 3TC. After the Week 48 analysis, the study became un-blinded and subjects continued the optimal QD dose of 400 mg BMS-986001, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime through the rest of stage 1 and the completion of stage 2.

Reporting group title	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD

Reporting group description:

In Stage 1, subjects were administered a QD dose of 300 mg TDF, 600 mg EFV, and 300 mg 3TC under fasted conditions at bedtime. Dosing was open-label for TDF, EFV and 3TC. In Stage 2, subjects continued the treatment regimen from stage 1.

Serious adverse events	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 65 (10.77%)	7 / 67 (10.45%)	9 / 66 (13.64%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Hodgkin's disease			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Amyloidosis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysfunctional uterine bleeding			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital ulceration			

subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menorrhagia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pneumothorax			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Pericarditis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal perforation			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Drug-Induced liver injury			

subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic pain			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema nodosum			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipodystrophy acquired			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus bladder			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node tuberculosis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic inflammatory disease			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syphilis			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD		
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 99 (11.11%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hodgkin's disease			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			

subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Amyloidosis			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysfunctional uterine bleeding			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Genital ulceration			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Menorrhagia			

subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pneumothorax			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Major depression			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			

subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Pericarditis			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hiatus hernia			

subjects affected / exposed	0 / 99 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileal perforation				
subjects affected / exposed	0 / 99 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	0 / 99 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	0 / 99 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mouth ulceration				
subjects affected / exposed	0 / 99 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	0 / 99 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	1 / 99 (1.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Drug-Induced liver injury				
subjects affected / exposed	1 / 99 (1.01%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic pain				

subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erythema nodosum			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipodystrophy acquired			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Calculus bladder			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis			

subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disseminated tuberculosis			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lobar pneumonia			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymph node tuberculosis			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic inflammatory disease			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	0 / 99 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	0 / 99 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	1 / 99 (1.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Syphilis				
subjects affected / exposed	0 / 99 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	BMS-986001 100 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 200 mg QD + EFV 600 mg QD + 3TC 300 mg QD	BMS-986001 400 mg QD + EFV 600 mg QD + 3TC 300 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	59 / 65 (90.77%)	61 / 67 (91.04%)	60 / 66 (90.91%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	30 / 65 (46.15%)	32 / 67 (47.76%)	29 / 66 (43.94%)
occurrences (all)	34	35	35
Headache			
subjects affected / exposed	14 / 65 (21.54%)	16 / 67 (23.88%)	10 / 66 (15.15%)
occurrences (all)	18	21	13
Somnolence			
subjects affected / exposed	4 / 65 (6.15%)	1 / 67 (1.49%)	1 / 66 (1.52%)
occurrences (all)	6	1	1
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 65 (1.54%)	1 / 67 (1.49%)	4 / 66 (6.06%)
occurrences (all)	1	3	4
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 65 (3.08%)	5 / 67 (7.46%)	6 / 66 (9.09%)
occurrences (all)	2	5	6
Pyrexia			
subjects affected / exposed	2 / 65 (3.08%)	3 / 67 (4.48%)	1 / 66 (1.52%)
occurrences (all)	2	3	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	6 / 65 (9.23%)	2 / 67 (2.99%)	5 / 66 (7.58%)
occurrences (all)	6	2	5
Constipation			
subjects affected / exposed	2 / 65 (3.08%)	1 / 67 (1.49%)	4 / 66 (6.06%)
occurrences (all)	2	1	4
Diarrhoea			
subjects affected / exposed	12 / 65 (18.46%)	15 / 67 (22.39%)	8 / 66 (12.12%)
occurrences (all)	17	18	8
Dyspepsia			
subjects affected / exposed	4 / 65 (6.15%)	3 / 67 (4.48%)	4 / 66 (6.06%)
occurrences (all)	5	3	4
Haemorrhoids			
subjects affected / exposed	1 / 65 (1.54%)	4 / 67 (5.97%)	3 / 66 (4.55%)
occurrences (all)	1	4	3
Nausea			
subjects affected / exposed	7 / 65 (10.77%)	6 / 67 (8.96%)	4 / 66 (6.06%)
occurrences (all)	7	6	4
Vomiting			
subjects affected / exposed	2 / 65 (3.08%)	1 / 67 (1.49%)	4 / 66 (6.06%)
occurrences (all)	2	1	4

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 65 (6.15%)	4 / 67 (5.97%)	3 / 66 (4.55%)
occurrences (all)	4	4	4
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	5 / 65 (7.69%)	4 / 67 (5.97%)	1 / 66 (1.52%)
occurrences (all)	5	7	1
Rash			
subjects affected / exposed	14 / 65 (21.54%)	10 / 67 (14.93%)	12 / 66 (18.18%)
occurrences (all)	19	12	12
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	6 / 65 (9.23%)	2 / 67 (2.99%)	1 / 66 (1.52%)
occurrences (all)	6	2	1
Insomnia			
subjects affected / exposed	2 / 65 (3.08%)	2 / 67 (2.99%)	4 / 66 (6.06%)
occurrences (all)	2	3	4
Nightmare			
subjects affected / exposed	3 / 65 (4.62%)	4 / 67 (5.97%)	1 / 66 (1.52%)
occurrences (all)	3	4	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 65 (3.08%)	3 / 67 (4.48%)	7 / 66 (10.61%)
occurrences (all)	2	3	9
Back pain			
subjects affected / exposed	5 / 65 (7.69%)	5 / 67 (7.46%)	8 / 66 (12.12%)
occurrences (all)	5	5	10
Osteopenia			
subjects affected / exposed	2 / 65 (3.08%)	2 / 67 (2.99%)	1 / 66 (1.52%)
occurrences (all)	2	2	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	4 / 65 (6.15%)	1 / 67 (1.49%)	3 / 66 (4.55%)
occurrences (all)	4	1	3
Conjunctivitis			

subjects affected / exposed	5 / 65 (7.69%)	3 / 67 (4.48%)	3 / 66 (4.55%)
occurrences (all)	7	3	4
Folliculitis			
subjects affected / exposed	1 / 65 (1.54%)	1 / 67 (1.49%)	1 / 66 (1.52%)
occurrences (all)	1	2	1
Furuncle			
subjects affected / exposed	4 / 65 (6.15%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences (all)	4	0	1
Gastroenteritis			
subjects affected / exposed	2 / 65 (3.08%)	4 / 67 (5.97%)	3 / 66 (4.55%)
occurrences (all)	2	5	3
Herpes zoster			
subjects affected / exposed	3 / 65 (4.62%)	0 / 67 (0.00%)	6 / 66 (9.09%)
occurrences (all)	3	0	6
Influenza			
subjects affected / exposed	9 / 65 (13.85%)	14 / 67 (20.90%)	13 / 66 (19.70%)
occurrences (all)	10	27	18
Lower respiratory tract infection			
subjects affected / exposed	1 / 65 (1.54%)	1 / 67 (1.49%)	3 / 66 (4.55%)
occurrences (all)	1	1	3
Nasopharyngitis			
subjects affected / exposed	4 / 65 (6.15%)	2 / 67 (2.99%)	3 / 66 (4.55%)
occurrences (all)	6	4	5
Otitis media			
subjects affected / exposed	4 / 65 (6.15%)	3 / 67 (4.48%)	0 / 66 (0.00%)
occurrences (all)	4	3	0
Tonsillitis			
subjects affected / exposed	6 / 65 (9.23%)	0 / 67 (0.00%)	1 / 66 (1.52%)
occurrences (all)	7	0	1
Upper respiratory tract infection			
subjects affected / exposed	17 / 65 (26.15%)	12 / 67 (17.91%)	16 / 66 (24.24%)
occurrences (all)	31	15	24
Urinary tract infection			
subjects affected / exposed	4 / 65 (6.15%)	10 / 67 (14.93%)	4 / 66 (6.06%)
occurrences (all)	6	13	5
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	2 / 65 (3.08%)	2 / 67 (2.99%)	4 / 66 (6.06%)
occurrences (all)	2	2	6
Hypercholesterolaemia			
subjects affected / exposed	5 / 65 (7.69%)	4 / 67 (5.97%)	5 / 66 (7.58%)
occurrences (all)	6	6	9

Non-serious adverse events	TDF 300 mg QD + EFV 600 mg QD + 3TC 300 mg QD		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	88 / 99 (88.89%)		
Nervous system disorders			
Dizziness			
subjects affected / exposed	38 / 99 (38.38%)		
occurrences (all)	40		
Headache			
subjects affected / exposed	23 / 99 (23.23%)		
occurrences (all)	27		
Somnolence			
subjects affected / exposed	3 / 99 (3.03%)		
occurrences (all)	3		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 99 (3.03%)		
occurrences (all)	4		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 99 (8.08%)		
occurrences (all)	8		
Pyrexia			
subjects affected / exposed	7 / 99 (7.07%)		
occurrences (all)	7		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	5 / 99 (5.05%)		
occurrences (all)	5		
Gastrointestinal disorders			

Abdominal pain subjects affected / exposed occurrences (all)	3 / 99 (3.03%) 3		
Constipation subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0		
Diarrhoea subjects affected / exposed occurrences (all)	14 / 99 (14.14%) 15		
Dyspepsia subjects affected / exposed occurrences (all)	3 / 99 (3.03%) 3		
Haemorrhoids subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1		
Nausea subjects affected / exposed occurrences (all)	7 / 99 (7.07%) 11		
Vomiting subjects affected / exposed occurrences (all)	4 / 99 (4.04%) 4		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	10 / 99 (10.10%) 10		
Skin and subcutaneous tissue disorders Dermatitis subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1		
Rash subjects affected / exposed occurrences (all)	12 / 99 (12.12%) 12		
Psychiatric disorders Abnormal dreams subjects affected / exposed occurrences (all)	7 / 99 (7.07%) 7		

Insomnia			
subjects affected / exposed	7 / 99 (7.07%)		
occurrences (all)	9		
Nightmare			
subjects affected / exposed	3 / 99 (3.03%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	6 / 99 (6.06%)		
occurrences (all)	6		
Osteopenia			
subjects affected / exposed	9 / 99 (9.09%)		
occurrences (all)	9		
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 99 (3.03%)		
occurrences (all)	3		
Conjunctivitis			
subjects affected / exposed	3 / 99 (3.03%)		
occurrences (all)	3		
Folliculitis			
subjects affected / exposed	5 / 99 (5.05%)		
occurrences (all)	7		
Furuncle			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	8 / 99 (8.08%)		
occurrences (all)	8		
Herpes zoster			
subjects affected / exposed	3 / 99 (3.03%)		
occurrences (all)	3		
Influenza			

subjects affected / exposed occurrences (all)	8 / 99 (8.08%) 15		
Lower respiratory tract infection subjects affected / exposed occurrences (all)	5 / 99 (5.05%) 6		
Nasopharyngitis subjects affected / exposed occurrences (all)	6 / 99 (6.06%) 13		
Otitis media subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 2		
Tonsillitis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	12 / 99 (12.12%) 15		
Urinary tract infection subjects affected / exposed occurrences (all)	3 / 99 (3.03%) 3		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	7 / 99 (7.07%) 8		
Hypercholesterolaemia subjects affected / exposed occurrences (all)	2 / 99 (2.02%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 October 2011	This amendment made the following changes: - Defined in the Synopsis that BMS-986001 is an NRTI - Further clarified throughout the protocol that TDF, EFV and 3TC are all open label, regardless of treatment group in which they were used - Additionally excluded subjects with resistance to HIV protease inhibitors and included a list of exclusionary PI mutations - Clarified among the secondary endpoints that "genotypic substitutions" referred to "drug resistance genotypic substitutions" - Clarified that safety and tolerability were assessed through AE collection, laboratory tests, and toxicity biomarkers - Inserted guidelines for the management of subjects in the event that a BMS-986001 treatment group was determined to be suboptimal prior to the selection of the optimal dose, as well as for subjects who had HIV RNA ≥ 200 c/mL after Week 48. Included additional exclusionary resistance mutations for EFV, TDF, and 3TC - Corrected the identification of CD4+ and CD8+ T-cell lab assessments and location for skin biopsies - Clarified the Stopping Guidelines intended to be Stopping Rules - Addressed administrative and/or typographical changes/errors
04 June 2012	This amendment addressed 3 primary changes to the protocol: monitoring study subjects for the development of thrombocytopenia based on preclinical findings in 3 monkeys, allowing treatment with rifampin for subjects who developed TB while on study, and excluding anemic subjects from participation in the optional Week 2 Intensive PK visit.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Based on data through Week 48, BMS determined BMS-986001 did not meet the desired drug attributes and target profile established by BMS to warrant continued development. BMS elected to terminate the study after all subjects had completed Week 48.

Notes: