



Clinical trial results:

A Phase IIb Randomized, Controlled, Partially Blinded Clinical Trial to Investigate Safety, Efficacy and Dose-response of BMS-986001 in Treatment-naïve 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-naïve 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 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 \geq 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 \geq 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 occurrences (all) | 1 / 65 (1.54%) 1 | 1 / 67 (1.49%) 3 | 4 / 66 (6.06%) 4 |
| General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all) | 2 / 65 (3.08%) 2 2 / 65 (3.08%) 2 | 5 / 67 (7.46%) 5 3 / 67 (4.48%) 3 | 6 / 66 (9.09%) 6 1 / 66 (1.52%) 1 |
| Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all) | 1 / 65 (1.54%) 1 | 0 / 67 (0.00%) 0 | 1 / 66 (1.52%) 1 |
| Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Dyspepsia subjects affected / exposed occurrences (all) Haemorrhoids subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all) | 6 / 65 (9.23%) 6 2 / 65 (3.08%) 2 12 / 65 (18.46%) 17 4 / 65 (6.15%) 5 1 / 65 (1.54%) 1 7 / 65 (10.77%) 7 2 / 65 (3.08%) 2 | 2 / 67 (2.99%) 2 1 / 67 (1.49%) 1 15 / 67 (22.39%) 18 3 / 67 (4.48%) 3 4 / 67 (5.97%) 4 6 / 67 (8.96%) 6 1 / 67 (1.49%) 1 | 5 / 66 (7.58%) 5 4 / 66 (6.06%) 4 8 / 66 (12.12%) 8 4 / 66 (6.06%) 4 3 / 66 (4.55%) 3 4 / 66 (6.06%) 4 4 / 66 (6.06%) 4 |

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

| | | | |
|------------------------------------|------------------|------------------|------------------|
| 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 occurrences (all) | 2 / 65 (3.08%) 2 | 2 / 67 (2.99%) 2 | 4 / 66 (6.06%) 6 |
| Hypercholesterolaemia subjects affected / exposed occurrences (all) | 5 / 65 (7.69%) 6 | 4 / 67 (5.97%) 6 | 5 / 66 (7.58%) 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 occurrences (all) Headache subjects affected / exposed occurrences (all) Somnolence subjects affected / exposed occurrences (all) | 38 / 99 (38.38%) 40 23 / 99 (23.23%) 27 3 / 99 (3.03%) 3 | | |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 3 / 99 (3.03%) 4 | | |
| General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all) | 8 / 99 (8.08%) 8 7 / 99 (7.07%) 7 | | |
| Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all) | 5 / 99 (5.05%) 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) Rash subjects affected / exposed occurrences (all) | 1 / 99 (1.01%) 1 12 / 99 (12.12%) 12 | | |
| Psychiatric disorders Abnormal dreams subjects affected / exposed occurrences (all) | 7 / 99 (7.07%) 7 | | |

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|--|
| 11 October 2011 | <p>This amendment made the following changes:</p> <ul style="list-style-type: none">- 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 \geq 200 c/mL after Week 48. <p>Included additional exclusionary resistance mutations for EFV, TDF, and 3TC</p> <ul style="list-style-type: none">- 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 | <p>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.</p> |

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: