



Clinical trial results:

A Phase 3 Randomized, Open Label Study to Evaluate Switching from Regimens Consisting of a Ritonavir-boosted Protease Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors to Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate (FTC/RPV/TDF) Fixed-dose Regimen in Virologically Suppressed, HIV-1 Infected Patients

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2010-023178-37 |
| Trial protocol | GB DE ES BE IT AT |
| Global end of trial date | 28 October 2014 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 05 June 2016 |
| First version publication date | 05 June 2016 |

Trial information

Trial identification

| | |
|-----------------------|----------------|
| Sponsor protocol code | GS-US-264-0106 |
|-----------------------|----------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01252940 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---------------------------------------------------------------------------------------------------|
| Sponsor organisation name | Gilead Sciences |
| Sponsor organisation address | 333 Lakeside Drive, Foster City, CA, United States, 94404 |
| Public contact | Clinical Trial Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.com |
| Scientific contact | Clinical Trial Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.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 | 28 October 2014 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 28 October 2014 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the non-inferiority of emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg (FTC/RPV/TDF) formulated as a single-tablet regimen (STR) and taken once daily relative to regimens consisting of a ritonavir-boosted protease inhibitor (PI/r) and 2 nucleoside reverse transcriptase inhibitors (NRTIs) in maintaining HIV-1 RNA < 50 copies/mL at Week 24.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.

This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

| | |
|-----------------------------------------------------------|------------------|
| Actual start date of recruitment | 17 November 2010 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Spain: 20 |
| Country: Number of subjects enrolled | United Kingdom: 23 |
| Country: Number of subjects enrolled | Austria: 26 |
| Country: Number of subjects enrolled | Belgium: 28 |
| Country: Number of subjects enrolled | France: 43 |
| Country: Number of subjects enrolled | Germany: 43 |
| Country: Number of subjects enrolled | Italy: 26 |
| Country: Number of subjects enrolled | Canada: 25 |
| Country: Number of subjects enrolled | Puerto Rico: 18 |
| Country: Number of subjects enrolled | United States: 230 |
| Worldwide total number of subjects | 482 |
| EEA total number of subjects | 209 |

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) | 477 |
| From 65 to 84 years | 5 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at 110 sites in the North America and Europe. The first participant was screened on 17 November 2010. The last participant observation was on 28 October 2014.

Pre-assignment

Screening details:

617 participants were screened.

Period 1

| | |
|------------------------------|-------------------------|
| Period 1 title | Main Study Phase |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|-------------|
| Are arms mutually exclusive? | Yes |
| Arm title | FTC/RPV/TDF |

Arm description:

Participants were randomized to switch from their existing treatment regimen to the emtricitabine (FTC)/rilpivirine (RPV)/tenofovir disoproxil fumarate (TDF) single-tablet regimen (STR) at the beginning of the study.

| | |
|----------------------------------------|---------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Emtricitabine/rilpivirine/tenofovir disoproxil fumarate |
| Investigational medicinal product code | |
| Other name | Complera®, Eviplera® |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Emtricitabine/rilpivirine/tenofovir disoproxil fumarate (FTC/RPV/TDF) 200/25/300 mg single-tablet regimen (STR) administered orally with a meal once daily

| | |
|------------------|--------------------|
| Arm title | SBR/Delayed Switch |
|------------------|--------------------|

Arm description:

Participants were randomized to stay on their existing treatment regimen (Stay on Baseline Regimen (SBR)) at the beginning of the study through Week 24, and switch to the FTC/RPV/TDF STR (Delayed Switch) at the Week 24 visit. Their existing treatment regimen consisted of protease inhibitor (PI) + ritonavir (RTV) + 2 two nucleoside reverse transcriptase inhibitors (NRTIs). Protease inhibitors (PIs) may have included amprenavir, atazanavir, darunavir, fosamprenavir, Kaletra (lopinavir/ritonavir, coformulated), ritonavir, and saquinavir. PIs were administered according to prescribing information. Ritonavir (RTV) was administered according to prescribing information. NRTIs may have included abacavir, emtricitabine, Combivir (lamivudine/zidovudine, coformulated), Epzicom (abacavir/lamivudine, coformulated), lamivudine, stavudine, tenofovir DF, Truvada® (emtricitabine/tenofovir DF, coformulated), and zidovudine. NRTIs were administered according to prescribing information.

| | |
|----------------------------------------|---------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Emtricitabine/rilpivirine/tenofovir disoproxil fumarate |
| Investigational medicinal product code | |
| Other name | Complera®, Eviplera® |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

FTC/RPV/TDF 200/25/300 mg STR administered orally with a meal once daily

| Number of subjects in period 1^[1] | FTC/RPV/TDF | SBR/Delayed Switch |
|-----------------------------------------------------|------------------|--------------------|
| Started | 317 | 159 |
| Completed 24 Weeks (SBR/Delayed Switch) | 0 ^[2] | 153 |
| Completed | 295 | 149 |
| Not completed | 22 | 10 |
| Physician decision | 1 | - |
| Adverse event, non-fatal | 3 | 1 |
| Subject Non-compliance | 1 | 1 |
| Withdrawal by Subject | 6 | 5 |
| Protocol Violation | 4 | 2 |
| Lost to follow-up | 6 | 1 |
| 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: 6 participants who were randomized but not treated are not included in the subject disposition table.

NOTE: For the SBR/Delayed Switch group, 152 participants switched regimens at Week 24.

Discontinuations after switch: withdrawal by subject = 2; adverse event = 1; and protocol violation = 1.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: This milestone only applies to the SBR/Delayed Switch group.

Period 2

| | |
|------------------------------|-----------------------------|
| Period 2 title | Extension Phase |
| Is this the baseline period? | No |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|-------------|
| Are arms mutually exclusive? | Yes |
| Arm title | FTC/RPV/TDF |

Arm description:

Participants were randomized to switch from their existing treatment regimen to the FTC/RPV/TDF STR at the beginning of the study. Following Week 48, participants may have continued to receive FTC/RPV/TDF STR per protocol before switching to a commercially available source.

| | |
|----------------------------------------|---------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Emtricitabine/rilpivirine/tenofovir disoproxil fumarate |
| Investigational medicinal product code | |
| Other name | Complera®, Eviplera® |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

FTC/RPV/TDF 200/25/300 mg STR administered orally with a meal once daily

| | |
|------------------|--------------------|
| Arm title | SBR/Delayed Switch |
|------------------|--------------------|

Arm description:

Participants were randomized to stay on their existing treatment regimen at the beginning of the study through Week 24, and switch to the FTC/RPV/TDF STR (Delayed Switch) at the Week 24 visit. Their existing treatment regimen consisted of PI+RTV+ 2 two NRTIs. PIs may have included amprenavir, atazanavir, darunavir, fosamprenavir, Kaletra (lopinavir/ritonavir, coformulated), ritonavir, and saquinavir. PIs were administered according to prescribing information. RTV was administered according to prescribing information. NRTIs may have included abacavir, emtricitabine, Combivir (lamivudine/zidovudine, coformulated), Epzicom (abacavir/lamivudine, coformulated), lamivudine, stavudine, tenofovir DF, Truvada® (emtricitabine/tenofovir DF, coformulated), and zidovudine. NRTIs were administered according to prescribing information.

Following Week 48, participants may have continued to receive FTC/RPV/TDF STR per protocol before switching to a commercially available source.

| | |
|----------------------------------------|---------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Emtricitabine/rilpivirine/tenofovir disoproxil fumarate |
| Investigational medicinal product code | |
| Other name | Complera®, Eviplera® |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

FTC/RPV/TDF 200/25/300 mg STR administered orally with a meal once daily

| Number of subjects in period 2^[3] | FTC/RPV/TDF | SBR/Delayed Switch |
|-----------------------------------------------------|-------------|--------------------|
| Started | 110 | 49 |
| Completed | 100 | 46 |
| Not completed | 10 | 3 |
| Physician decision | - | 1 |
| Adverse event, non-fatal | 2 | 1 |
| Subject Non-compliance | 1 | - |
| Withdrawal by Subject | 1 | 1 |
| Lost to follow-up | 5 | - |
| Lack of efficacy | 1 | - |

Notes:

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

Justification: FTC/RPV/TDF group: 110 participants completing the main study continued in extension phase.

SBR/Delayed Switch Group: 49 participants completing the main study continued in extension phase.

Baseline characteristics

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | FTC/RPV/TDF |
|-----------------------|-------------|

Reporting group description:

Participants were randomized to switch from their existing treatment regimen to the emtricitabine (FTC)/rilpivirine (RPV)/tenofovir disoproxil fumarate (TDF) single-tablet regimen (STR) at the beginning of the study.

| | |
|-----------------------|--------------------|
| Reporting group title | SBR/Delayed Switch |
|-----------------------|--------------------|

Reporting group description:

Participants were randomized to stay on their existing treatment regimen (Stay on Baseline Regimen (SBR)) at the beginning of the study through Week 24, and switch to the FTC/RPV/TDF STR (Delayed Switch) at the Week 24 visit. Their existing treatment regimen consisted of protease inhibitor (PI) + ritonavir (RTV) + 2 two nucleoside reverse transcriptase inhibitors (NRTIs). Protease inhibitors (PIs) may have included amprenavir, atazanavir, darunavir, fosamprenavir, Kaletra (lopinavir/ritonavir, coformulated), ritonavir, and saquinavir. PIs were administered according to prescribing information. Ritonavir (RTV) was administered according to prescribing information. NRTIs may have included abacavir, emtricitabine, Combivir (lamivudine/zidovudine, coformulated), Epzicom (abacavir/lamivudine, coformulated), lamivudine, stavudine, tenofovir DF, Truvada® (emtricitabine/tenofovir DF, coformulated), and zidovudine. NRTIs were administered according to prescribing information.

| Reporting group values | FTC/RPV/TDF | SBR/Delayed Switch | Total |
|------------------------------------|-------------|--------------------|-------|
| Number of subjects | 317 | 159 | 476 |
| Age categorical Units: Subjects | | | |

| | | | |
|------------------------------------------------|-------|-------|-----|
| Age continuous Units: years | | | |
| arithmetic mean | 41 | 43 | |
| standard deviation | ± 9.2 | ± 9.7 | - |
| Gender categorical Units: Subjects | | | |
| Female | 44 | 15 | 59 |
| Male | 273 | 144 | 417 |
| Ethnicity Units: Subjects | | | |
| Hispanic or Latino | 51 | 31 | 82 |
| Not Hispanic or Latino | 264 | 128 | 392 |
| Unknown or Not Reported | 2 | 0 | 2 |
| Race Units: Subjects | | | |
| White | 241 | 124 | 365 |
| Black or African American | 61 | 22 | 83 |
| American Indian or Alaska Native | 3 | 2 | 5 |
| Asian | 6 | 2 | 8 |
| Other | 6 | 9 | 15 |
| Baseline HIV-1 RNA Category Units: Subjects | | | |
| < 50 Copies/mL | 299 | 152 | 451 |
| 50 to < 200 Copies/mL | 10 | 6 | 16 |
| 200 to < 400 Copies/mL | 2 | 0 | 2 |
| 400 to < 1000 Copies/mL | 2 | 0 | 2 |

| ≥ 1000 Copies/mL | 4 | 1 | 5 |
|---------------------------------------------------|-----|----|-----|
| Stratification based on antiretroviral (ARV) use | | | |
| Units: Subjects | | | |
| TDF or FTC/TDF + lopinavir (LPV) /ritonavir (RTV) | 82 | 49 | 131 |
| TDF or FTC/TDF + Other PI +RTV | 178 | 81 | 259 |
| Non-TDF-containing regimen + LPV/RTV | 15 | 9 | 24 |
| Non-TDF-containing regimen + Other PI+RTV | 42 | 20 | 62 |

End points

End points reporting groups

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Reporting group title | FTC/RPV/TDF |
| Reporting group description: Participants were randomized to switch from their existing treatment regimen to the emtricitabine (FTC)/rilpivirine (RPV)/tenofovir disoproxil fumarate (TDF) single-tablet regimen (STR) at the beginning of the study. | |
| Reporting group title | SBR/Delayed Switch |
| Reporting group description: Participants were randomized to stay on their existing treatment regimen (Stay on Baseline Regimen (SBR)) at the beginning of the study through Week 24, and switch to the FTC/RPV/TDF STR (Delayed Switch) at the Week 24 visit. Their existing treatment regimen consisted of protease inhibitor (PI) + ritonavir (RTV) + 2 two nucleoside reverse transcriptase inhibitors (NRTIs). Protease inhibitors (PIs) may have included amprenavir, atazanavir, darunavir, fosamprenavir, Kaletra (lopinavir/ritonavir, coformulated), ritonavir, and saquinavir. PIs were administered according to prescribing information. Ritonavir (RTV) was administered according to prescribing information. NRTIs may have included abacavir, emtricitabine, Combivir (lamivudine/zidovudine, coformulated), Epzicom (abacavir/lamivudine, coformulated), lamivudine, stavudine, tenofovir DF, Truvada® (emtricitabine/tenofovir DF, coformulated), and zidovudine. NRTIs were administered according to prescribing information. | |
| Reporting group title | FTC/RPV/TDF |
| Reporting group description: Participants were randomized to switch from their existing treatment regimen to the FTC/RPV/TDF STR at the beginning of the study. Following Week 48, participants may have continued to receive FTC/RPV/TDF STR per protocol before switching to a commercially available source. | |
| Reporting group title | SBR/Delayed Switch |
| Reporting group description: Participants were randomized to stay on their existing treatment regimen at the beginning of the study through Week 24, and switch to the FTC/RPV/TDF STR (Delayed Switch) at the Week 24 visit. Their existing treatment regimen consisted of PI+RTV+ 2 two NRTIs. PIs may have included amprenavir, atazanavir, darunavir, fosamprenavir, Kaletra (lopinavir/ritonavir, coformulated), ritonavir, and saquinavir. PIs were administered according to prescribing information. RTV was administered according to prescribing information. NRTIs may have included abacavir, emtricitabine, Combivir (lamivudine/zidovudine, coformulated), Epzicom (abacavir/lamivudine, coformulated), lamivudine, stavudine, tenofovir DF, Truvada® (emtricitabine/tenofovir DF, coformulated), and zidovudine. NRTIs were administered according to prescribing information. | |
| Following Week 48, participants may have continued to receive FTC/RPV/TDF STR per protocol before switching to a commercially available source. | |

Primary: Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 24 (FDA Snapshot Analysis)

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 24 (FDA Snapshot Analysis) |
| End point description: The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed using the FDA snapshot analysis. | |
| Full Analysis Set: participants who were randomized into the study and received at least one dose of study drug. | |
| End point type | Primary |
| End point timeframe: Week 24 | |

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|-----------------------------------|-----------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 317 | 159 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 93.7 | 89.9 | | |

Statistical analyses

| Statistical analysis title | HIV-1 RNA < 50 Copies/mL at Week 24 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Statistical analysis description: | |
| A 95% confidence interval (CI) for the difference between treatment groups in the percentages of virologic success was constructed using normal approximation. Noninferiority was assessed using a conventional 95% CI approach, with a noninferiority margin of 12%. It would be concluded that the FTC/RPV/TDF STR group was not inferior to the SBR group if the lower bound of the 2-sided 95% CI of the difference (FTC/RPV/TDF STR – SBR) in the response rate was greater than -12%. | |
| Comparison groups | FTC/RPV/TDF v SBR/Delayed Switch |
| Number of subjects included in analysis | 476 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | Mean difference (net) |
| Point estimate | 3.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.6 |
| upper limit | 9.1 |

Secondary: Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 48 (FDA Snapshot Analysis)

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 48 (FDA Snapshot Analysis) |
| End point description: | |
| The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed using the FDA snapshot analysis. By Week 48, participants FTC/RPV/TDF had received 48 weeks of treatment with FTC/RPV/TDF, while those in the SBR/Delayed Switch group had received only 24 weeks of treatment with FTC/RPV/TDF. | |
| Participants in the Full Analysis Set in the FTC/RPV/TDF and the Delayed Switch to FTC/RPV/TDF groups were analyzed. | |
| End point type | Secondary |
| End point timeframe: | |
| Week 48 | |

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|-----------------------------------|-----------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 317 | 152 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 89.3 | 92.1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Cluster of Differentiation 4 (CD4) Count Through Week 24

| | |
|-----------------|----------------------------------------------------------------------------------|
| End point title | Change From Baseline in Cluster of Differentiation 4 (CD4) Count Through Week 24 |
|-----------------|----------------------------------------------------------------------------------|

End point description:

The mean (SD) change in CD4 count was analyzed from baseline through Week 24.

Participants in the Full Analysis Set who had CD4 measurements at both baseline and Week 24 were analyzed.

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

End point timeframe:

Baseline to Week 24

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|-----------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 298 | 148 | | |
| Units: cells/mm ³ | | | | |
| arithmetic mean (standard deviation) | 20 (± 149.3) | 32 (± 158.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in CD4 Count Through Week 48

| | |
|-----------------|---------------------------------------------------|
| End point title | Change From Baseline in CD4 Count Through Week 48 |
|-----------------|---------------------------------------------------|

End point description:

The mean (SD) change in CD4 count was analyzed from baseline through Week 48. By Week 48, participants FTC/RPV/TDF had received 48 weeks of treatment with FTC/RPV/TDF, while those in the SBR/Delayed Switch group had received only 24 weeks of treatment with FTC/RPV/TDF.

Participants in the Full Analysis Set who had CD4 measurements at both baseline and Week 48 were analyzed.

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

End point timeframe:

Baseline to Week 48

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|-----------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 287 | 143 | | |
| Units: cells/mm ³ | | | | |
| arithmetic mean (standard deviation) | 10 (± 144.1) | -7 (± 154.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fasting Total Cholesterol Through Week 24

| | |
|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| End point title | Change From Baseline in Fasting Total Cholesterol Through Week 24 |
| End point description: | |
| The mean (SD) change from baseline in fasting total cholesterol (mg/dL) through Week 24 was analyzed. | |
| Participants in the Safety Analysis Set who had measurements for total cholesterol at both baseline and Week 24 were analyzed. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline to Week 24 | |

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|-----------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 269 | 134 | | |
| Units: mg/dL | | | | |
| arithmetic mean (standard deviation) | -25 (± 30.2) | -1 (± 25.9) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fasting Total Cholesterol Through Week 48

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| End point title | Change From Baseline in Fasting Total Cholesterol Through Week 48 |
| End point description: | |
| The mean (SD) change from baseline in fasting total cholesterol (mg/dL) through Week 48 was analyzed. By Week 48, participants FTC/RPV/TDF had received 48 weeks of treatment with FTC/RPV/TDF, while those in the SBR/Delayed Switch group had received only 24 weeks of treatment with FTC/RPV/TDF. | |

Participants in the Safety Analysis Set who had measurements for total cholesterol at both baseline and Week 48 were analyzed.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline to Week 48 | |

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|-------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 265 | 139 | | |
| Units: mg/dL | | | | |
| arithmetic mean (standard deviation) | -24 (\pm 32.9) | -24 (\pm 32) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fasting High-density Lipoprotein (HDL) Cholesterol Through Week 24

| | |
|-----------------|--------------------------------------------------------------------------------------------|
| End point title | Change From Baseline in Fasting High-density Lipoprotein (HDL) Cholesterol Through Week 24 |
|-----------------|--------------------------------------------------------------------------------------------|

End point description:

The mean (SD) change from baseline in fasting HDL cholesterol (mg/dL) through Week 24 was analyzed.

Participants in the Safety Analysis Set who had measurements for HDL cholesterol at both baseline and Week 24 were analyzed.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline to Week 24 | |

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 269 | 134 | | |
| Units: mg/dL | | | | |
| arithmetic mean (standard deviation) | -4 (\pm 10.3) | -1 (\pm 8.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fasting HDL Cholesterol Through Week 48

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| End point title | Change From Baseline in Fasting HDL Cholesterol Through Week 48 |
| End point description: The mean (SD) change from baseline in fasting HDL cholesterol (mg/dL) through Week 48 was analyzed. By Week 48, participants FTC/RPV/TDF had received 48 weeks of treatment with FTC/RPV/TDF, while those in the SBR/Delayed Switch group had received only 24 weeks of treatment with FTC/RPV/TDF. | |
| End point type | Secondary |
| End point timeframe: Baseline to Week 48 | |

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 265 | 139 | | |
| Units: mg/dL | | | | |
| arithmetic mean (standard deviation) | -2 (\pm 11.6) | -2 (\pm 8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fasting Direct Low-density Lipoprotein (LDL) Cholesterol Through Week 24

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| End point title | Change From Baseline in Fasting Direct Low-density Lipoprotein (LDL) Cholesterol Through Week 24 |
| End point description: The mean (SD) change from baseline in fasting direct LDL cholesterol (mg/dL) through Week 24 was analyzed. Participants in the Safety Analysis Set who had measurements for direct LDL cholesterol at both baseline and Week 24 were analyzed. | |
| End point type | Secondary |
| End point timeframe: Baseline to Week 24 | |

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|-------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 270 | 134 | | |
| Units: mg/dL | | | | |
| arithmetic mean (standard deviation) | -16 (\pm 25.6) | 0 (\pm 23.7) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fasting Direct LDL Cholesterol Through Week 48

| | |
|-----------------|------------------------------------------------------------------------|
| End point title | Change From Baseline in Fasting Direct LDL Cholesterol Through Week 48 |
|-----------------|------------------------------------------------------------------------|

End point description:

The mean (SD) change from baseline in fasting direct LDL cholesterol (mg/dL) through Week 48 was analyzed. By Week 48, participants FTC/RPV/TDF had received 48 weeks of treatment with FTC/RPV/TDF, while those in the SBR/Delayed Switch group had received only 24 weeks of treatment with FTC/RPV/TDF.

Participants in the Safety Analysis Set who had measurements for direct LDL cholesterol at both baseline and Week 48 were analyzed.

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

End point timeframe:

Baseline to Week 48

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|-------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 265 | 139 | | |
| Units: mg/dL | | | | |
| arithmetic mean (standard deviation) | -16 (\pm 27.1) | -14 (\pm 26.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fasting Triglycerides Through Week 24

| | |
|-----------------|---------------------------------------------------------------|
| End point title | Change From Baseline in Fasting Triglycerides Through Week 24 |
|-----------------|---------------------------------------------------------------|

End point description:

The mean (SD) change from baseline in fasting triglycerides through Week 24 was analyzed.

Participants in the Safety Analysis Set who had measurements for triglycerides at both baseline and Week 24 were analyzed.

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

End point timeframe:

Baseline to Week 24

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|-----------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 269 | 134 | | |
| Units: mg/dL | | | | |
| arithmetic mean (standard deviation) | -53 (± 110) | 3 (± 100.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fasting Triglycerides Through Week 48

| | |
|-----------------|---------------------------------------------------------------|
| End point title | Change From Baseline in Fasting Triglycerides Through Week 48 |
|-----------------|---------------------------------------------------------------|

End point description:

The mean (SD) change from baseline in fasting triglycerides through Week 48 was analyzed. By Week 48, participants FTC/RPV/TDF had received 48 weeks of treatment with FTC/RPV/TDF, while those in the SBR/Delayed Switch group had received only 24 weeks of treatment with FTC/RPV/TDF.

Participants in the Safety Analysis Set who had measurements for triglycerides at both baseline and Week 48 were analyzed.

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

End point timeframe:

Baseline to Week 48

| End point values | FTC/RPV/TDF | SBR/Delayed Switch | | |
|--------------------------------------|-----------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 265 | 139 | | |
| Units: mg/dL | | | | |
| arithmetic mean (standard deviation) | -64 (± 126.4) | -80 (± 141.1) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline through end of study (average 54 weeks)

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 17.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | FTC/RPV/TDF |
|-----------------------|-------------|

Reporting group description:

The adverse events reported in this group are those that occurred at any time during the study in participants who were randomized to switch from their existing treatment regimen to the FTC/RPV/TDF STR at the beginning of the study.

| | |
|-----------------------|------------------------------------|
| Reporting group title | SBR/Delayed Switch (up to Week 24) |
|-----------------------|------------------------------------|

Reporting group description:

The adverse events reported in this group are those that occurred in the first 24 weeks of the study in participants who were randomized to stay on their existing treatment regimen (Stay on Baseline Regimen (SBR)) at the beginning of the study and switch to the FTC/RPV/TDF STR (Delayed Switch) at the Week 24 visit.

| | |
|-----------------------|------------------------------------|
| Reporting group title | SBR/Delayed Switch (After Week 24) |
|-----------------------|------------------------------------|

Reporting group description:

The adverse events reported in this group are those that occurred after Week 24 in participants who were randomized to stay on their existing treatment regimen (Stay on Baseline Regimen (SBR)) at the beginning of the study and switch to the FTC/RPV/TDF STR (Delayed Switch) at Week 24 visit.

| Serious adverse events | FTC/RPV/TDF | SBR/Delayed Switch (up to Week 24) | SBR/Delayed Switch (After Week 24) |
|---------------------------------------------------------------------|------------------|------------------------------------|------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 21 / 317 (6.62%) | 8 / 159 (5.03%) | 9 / 152 (5.92%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign neoplasm of thyroid gland | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Arterial occlusive disease | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| General disorders and administration | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 1 / 159 (0.63%) | 0 / 152 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Prostatism | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute respiratory failure | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Asthma | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (0.00%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Psychiatric disorders | | | |
| Suicidal ideation | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bipolar disorder | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Substance-induced mood disorder | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Meniscus injury | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Stab wound | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 1 / 159 (0.63%) | 0 / 152 (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 |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Cardiac disorders | | | |
| Angina unstable | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| 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 | | | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Sensory loss | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Visual acuity reduced | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 1 / 159 (0.63%) | 0 / 152 (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 |
| Gastrointestinal disorders | | | |
| Gastrointestinal haemorrhage | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Nephropathy toxic | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal impairment | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Arthritis reactive | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bursitis | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Muscular weakness | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Polyarthritis | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 1 / 159 (0.63%) | 0 / 152 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pneumonia | | | |
| subjects affected / exposed | 3 / 317 (0.95%) | 0 / 159 (0.00%) | 0 / 152 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 1 / 159 (0.63%) | 0 / 152 (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 |
| Anal abscess | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 1 / 159 (0.63%) | 0 / 152 (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 |
| Lung infection | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Shigella infection | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 1 / 159 (0.63%) | 0 / 152 (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 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 0 / 159 (0.00%) | 1 / 152 (0.66%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urosepsis | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 1 / 159 (0.63%) | 0 / 152 (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 |
| Viral infection | | | |
| subjects affected / exposed | 1 / 317 (0.32%) | 0 / 159 (0.00%) | 0 / 152 (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 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 317 (0.00%) | 1 / 159 (0.63%) | 0 / 152 (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 |

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

| Non-serious adverse events | FTC/RPV/TDF | SBR/Delayed Switch (up to Week 24) | SBR/Delayed Switch (After Week 24) |
|-------------------------------------------------------|--------------------|-----------------------------------------------|-----------------------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 150 / 317 (47.32%) | 38 / 159 (23.90%) | 59 / 152 (38.82%) |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 31 / 317 (9.78%) | 6 / 159 (3.77%) | 6 / 152 (3.95%) |
| occurrences (all) | 37 | 6 | 8 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 22 / 317 (6.94%) | 5 / 159 (3.14%) | 4 / 152 (2.63%) |
| occurrences (all) | 22 | 5 | 4 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 34 / 317 (10.73%) | 8 / 159 (5.03%) | 6 / 152 (3.95%) |
| occurrences (all) | 37 | 8 | 7 |
| Nausea | | | |
| subjects affected / exposed | 13 / 317 (4.10%) | 5 / 159 (3.14%) | 10 / 152 (6.58%) |
| occurrences (all) | 13 | 5 | 10 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 23 / 317 (7.26%) | 1 / 159 (0.63%) | 2 / 152 (1.32%) |
| occurrences (all) | 23 | 1 | 2 |
| Psychiatric disorders | | | |
| Insomnia | | | |
| subjects affected / exposed | 21 / 317 (6.62%) | 3 / 159 (1.89%) | 9 / 152 (5.92%) |
| occurrences (all) | 21 | 3 | 9 |
| Depression | | | |
| subjects affected / exposed | 18 / 317 (5.68%) | 4 / 159 (2.52%) | 6 / 152 (3.95%) |
| occurrences (all) | 18 | 4 | 6 |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 13 / 317 (4.10%) | 6 / 159 (3.77%) | 8 / 152 (5.26%) |
| occurrences (all) | 16 | 6 | 8 |
| Arthralgia | | | |

| | | | |
|--------------------------------------------------|------------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 18 / 317 (5.68%) 19 | 2 / 159 (1.26%) 2 | 3 / 152 (1.97%) 3 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 35 / 317 (11.04%) | 8 / 159 (5.03%) | 12 / 152 (7.89%) |
| occurrences (all) | 44 | 10 | 13 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 15 / 317 (4.73%) | 5 / 159 (3.14%) | 13 / 152 (8.55%) |
| occurrences (all) | 15 | 5 | 18 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

| |
|--------------------------------------------------------------|
| There were no limitations affecting the analysis or results. |
|--------------------------------------------------------------|

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/2467052>