



Clinical trial results:

A Phase 3b, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV-1 Infected Subjects who are Virologically Suppressed on Regimens containing ABC/3TC

Summary

EudraCT number	2015-000871-28
Trial protocol	SE BE DE DK IE ES IT
Global end of trial date	13 March 2019

Results information

Result version number	v1 (current)
This version publication date	30 October 2019
First version publication date	30 October 2019

Trial information

Trial identification

Sponsor protocol code	GS-US-311-1717
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02469246
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	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com
Scientific contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@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	13 March 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 December 2017
Global end of trial reached?	Yes
Global end of trial date	13 March 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study were to evaluate the efficacy, safety, and tolerability of switching abacavir/lamivudine (ABC/3TC) fixed-dose combination (FDC) tablets to emtricitabine/tenofovir alafenamide (F/TAF) FDC tablets versus maintaining ABC/3TC in human immunodeficiency virus type 1 (HIV-1) infected adults who are virologically suppressed on regimens containing ABC/3TC.

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:

Participants received an allowed 3rd antiretroviral (ARV) agent of the participant's pre-existing regimen (boosted with F/TAF 200/10 mg FDC or unboosted with F/TAF 200/25 mg FDC). An allowed 3rd ARV agent of the participant's pre-existing regimen may have included one of the following boosted ARV agents: ritonavir boosted lopinavir (LPV/r), atazanavir (ATV) + ritonavir (RTV), ATV + cobicistat (COBI) or ATV/COBI FDC, darunavir (DRV) + RTV, DRV+COBI or DRV/COBI FDC; or, one of the following unboosted ARV agents: efavirenz (EFV), rilpivirine (RPV), raltegravir (RAL), dolutegravir (DTG), maraviroc (MVC), or nevirapine (NVP).

Evidence for comparator: -

Actual start date of recruitment	29 June 2015
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: 71
Country: Number of subjects enrolled	Sweden: 7
Country: Number of subjects enrolled	United Kingdom: 112
Country: Number of subjects enrolled	Belgium: 10
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	France: 36
Country: Number of subjects enrolled	Germany: 39
Country: Number of subjects enrolled	Ireland: 18

Country: Number of subjects enrolled	United States: 199
Country: Number of subjects enrolled	Canada: 17
Country: Number of subjects enrolled	Puerto Rico: 8
Country: Number of subjects enrolled	Italy: 43
Worldwide total number of subjects	567
EEA total number of subjects	343

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)	526
From 65 to 84 years	41
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in North America and Europe. The first participant was screened on 29 June 2015. The last study visit occurred on 13 March 2019.

Pre-assignment

Screening details:

626 participants were screened.

Period 1

Period 1 title	Double-Blind Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	F/TAF

Arm description:

Double-Blind Phase: F/TAF (200/10 mg) FDC tablet (with boosted 3rd ARV agent) or F/TAF (200/25 mg) FDC tablet (with unboosted 3rd ARV agent) + ABC/3TC placebo tablet once daily for 96 weeks

Arm type	Experimental
Investigational medicinal product name	Emtricitabine/tenofovir alafenamide
Investigational medicinal product code	
Other name	F/TAF; Descovy®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

200/10 mg FDC tablet (with boosted 3rd ARV agent) or 200/25 mg FDC tablet (with unboosted 3rd ARV agent) administered orally once daily

Investigational medicinal product name	ABC/3TC Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet administered orally once daily

Arm title	ABC/3TC
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Arm description:

Double-Blind Phase: ABC/3TC (600/300 mg) FDC tablet + F/TAF placebo tablet once daily + allowed 3rd ARV agent for 96 weeks.

Arm type	Active comparator
Investigational medicinal product name	Abacavir/lamivudine
Investigational medicinal product code	
Other name	ABC/3TC
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

600/300 mg FDC tablet administered orally once daily

Investigational medicinal product name	F/TAF Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet administered orally once daily

Number of subjects in period 1^[1]	F/TAF	ABC/3TC
Started	280	276
Completed	218	226
Not completed	62	50
Withdrew Consent	25	25
Adverse Event	12	9
Non-Compliance with Study Drug	3	1
Death	2	-
Investigator's Discretion	8	8
Protocol Violation	1	1
Lost to follow-up	9	5
Lack of efficacy	2	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: 11 participants (5 F/TAF; 6 ABC/3TC) who were randomized but not treated are not included in the subject disposition table.

Period 2

Period 2 title	Open-Label Extension (OLE)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	F/TAF to Open-Label F/TAF

Arm description:

Open-Label Extension: After the unblinding visit, in countries where F/TAF FDC was not commercially available, participants (except in certain countries) were given the option to receive the open-label F/TAF FDC and attend study visits every 12 weeks until it became commercially available, or until Gilead terminated the study in that country.

Arm type	Experimental
Investigational medicinal product name	Emtricitabine/tenofovir alafenamide
Investigational medicinal product code	
Other name	F/TAF; Descovy®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

200/10 mg FDC tablet (with boosted 3rd ARV agent) or 200/25 mg FDC tablet (with unboosted 3rd ARV agent) administered orally once daily

Arm title	ABC/3TC to Open-Label F/TAF
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Arm description:

Open-Label Extension: After the unblinding visit, in countries where F/TAF FDC was not commercially available, participants (except in certain countries) were given the option to receive the open-label F/TAF FDC and attend study visits every 12 weeks until it became commercially available, or until Gilead terminated the study in that country.

Arm type	Experimental
Investigational medicinal product name	Emtricitabine/tenofovir alafenamide
Investigational medicinal product code	
Other name	F/TAF; Descovy®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

200/10 mg FDC tablet (with boosted 3rd ARV agent) or 200/25 mg FDC tablet (with unboosted 3rd ARV agent) administered orally once daily

Number of subjects in period 2^[2]	F/TAF to Open-Label F/TAF	ABC/3TC to Open-Label F/TAF
Started	6	5
Completed	6	5

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: Only participants in countries where F/TAF was not commercially available were eligible for the OLE.

Baseline characteristics

Reporting groups

Reporting group title	F/TAF
Reporting group description:	
Double-Blind Phase: F/TAF (200/10 mg) FDC tablet (with boosted 3rd ARV agent) or F/TAF (200/25 mg) FDC tablet (with unboosted 3rd ARV agent) + ABC/3TC placebo tablet once daily for 96 weeks	
Reporting group title	ABC/3TC
Reporting group description:	
Double-Blind Phase: ABC/3TC (600/300 mg) FDC tablet + F/TAF placebo tablet once daily + allowed 3rd ARV agent for 96 weeks.	

Reporting group values	F/TAF	ABC/3TC	Total
Number of subjects	280	276	556
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	51	51	
standard deviation	± 9.4	± 9.3	-
Gender categorical Units: Subjects			
Female	40	61	101
Male	240	215	455
Race Units: Subjects			
American Indian or Alaska Native	1	0	1
Asian	5	5	10
Black	64	66	130
White	205	199	404
Other	5	6	11
Ethnicity Units: Subjects			
Hispanic or Latino	16	19	35
Not Hispanic or Latino	264	257	521
HIV-1 RNA Category Units: Subjects			
< 50 copies/mL	278	273	551
≥ 50 copies/mL	2	3	5
CD4 Cell Count Category Units: Subjects			
< 50 cells/μL	0	1	1
≥ 50 to < 200 cells/μL	0	0	0
≥ 200 to < 350 cells/μL	20	16	36
≥ 350 to < 500 cells/μL	56	38	94
≥ 500 cells/μL	204	221	425
HIV Disease Status Units: Subjects			

Asymptomatic	201	201	402
Symptomatic HIV Infection	31	24	55
AIDS	47	50	97
Unknown	1	1	2
CD4 Cell Count			
Units: cells/ μ L			
arithmetic mean	703	727	
standard deviation	± 298.7	± 275.2	-

End points

End points reporting groups

Reporting group title	F/TAF
Reporting group description: Double-Blind Phase: F/TAF (200/10 mg) FDC tablet (with boosted 3rd ARV agent) or F/TAF (200/25 mg) FDC tablet (with unboosted 3rd ARV agent) + ABC/3TC placebo tablet once daily for 96 weeks	
Reporting group title	ABC/3TC
Reporting group description: Double-Blind Phase: ABC/3TC (600/300 mg) FDC tablet + F/TAF placebo tablet once daily + allowed 3rd ARV agent for 96 weeks.	
Reporting group title	F/TAF to Open-Label F/TAF
Reporting group description: Open-Label Extension: After the unblinding visit, in countries where F/TAF FDC was not commercially available, participants (except in certain countries) were given the option to receive the open-label F/TAF FDC and attend study visits every 12 weeks until it became commercially available, or until Gilead terminated the study in that country.	
Reporting group title	ABC/3TC to Open-Label F/TAF
Reporting group description: Open-Label Extension: After the unblinding visit, in countries where F/TAF FDC was not commercially available, participants (except in certain countries) were given the option to receive the open-label F/TAF FDC and attend study visits every 12 weeks until it became commercially available, or until Gilead terminated the study in that country.	

Primary: Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 48 as Determined by the FDA-Defined Snapshot Algorithm

End point title	Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 48 as Determined by the FDA-Defined Snapshot Algorithm
End point description: The percentage of participants achieving HIV-1 RNA < 50 copies/mL at Week 48 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. The Full Analysis Set included all participants who were randomized into the study and received at least 1 dose of study drug. Participants were grouped according to the treatment to which they were randomized.	
End point type	Primary
End point timeframe: Week 48	

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	280	276		
Units: percentage of participants				
number (not applicable)	88.6	92.4		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
Statistical analysis description:	
The analysis purpose of the primary efficacy endpoint was to assess the noninferiority of switching to F/TAF+3rd Agent relative to maintaining treatment with ABC/3TC+3rd Agent. The difference in percentages and its 95.002% CI were calculated based on an unconditional exact method using 2 inverted 1-sided tests. Note that the confidence interval for the difference in percentages was actually 95.002%, but the EudraCT system automatically rounds the value to 95%.	
Comparison groups	F/TAF v ABC/3TC
Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
P-value	= 0.15
Method	Fisher exact
Parameter estimate	Difference in Percentages
Point estimate	-3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.9
upper limit	1.1

Notes:

[1] - Non-inferiority was assessed using a 2-sided exact 95% confidence interval (CI) approach, with a non-inferiority margin of 10%.

Secondary: Percentage of Participants With HIV-1 RNA $\geq$ 50 Copies/mL at Week 48 as Determined by the FDA-Defined Snapshot Algorithm

End point title	Percentage of Participants With HIV-1 RNA $\geq$ 50 Copies/mL at Week 48 as Determined by the FDA-Defined Snapshot Algorithm
End point description: The percentage of participants with HIV-1 RNA $\geq$ 50 copies/mL at Week 48 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.	
End point type	Secondary
End point timeframe: Week 48	

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	280	276		
Units: percentage of participants				
number (not applicable)	1.8	0.7		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
Statistical analysis description:	
The analysis purpose of this efficacy endpoint was to assess the non-inferiority of switching to	

F/TAF+3rd Agent relative to maintaining treatment with ABC/3TC+3rd Agent. The difference in percentages and its 95.002% CI were calculated based on an unconditional exact method using 2 inverted 1-sided tests. Note that the confidence interval for the difference in percentages was actually 95.002%, but the EudraCT system automatically rounds the value to 95%.

Comparison groups	F/TAF v ABC/3TC
Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[2]
P-value	= 0.45
Method	Fisher exact
Parameter estimate	Difference in Percentages
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	3.5

Notes:

[2] - Non-inferiority was assessed using a 2-sided exact 95% CI approach, with a non-inferiority margin of 4%.

Secondary: Percentage of Participants With HIV-1 RNA $\geq$ 50 Copies/mL at Week 96 as Determined by the FDA-Defined Snapshot Algorithm

End point title	Percentage of Participants With HIV-1 RNA $\geq$ 50 Copies/mL at Week 96 as Determined by the FDA-Defined Snapshot Algorithm
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End point description:

The percentage of participants with HIV-1 RNA $\geq$ 50 copies/mL at Week 96 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

End point type	Secondary
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End point timeframe:

Week 96

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	280	276		
Units: percentage of participants				
number (not applicable)	2.5	1.1		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
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Statistical analysis description:

The analysis purpose of this efficacy endpoint was to assess the non-inferiority of switching to F/TAF+3rd Agent relative to maintaining treatment with ABC/3TC+3rd Agent. The difference in percentages and its 95% CI were calculated based on an unconditional exact method using 2 inverted 1-sided tests.

Comparison groups	F/TAF v ABC/3TC
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Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[3]
P-value	= 0.34
Method	Fisher exact
Parameter estimate	Difference in Percentages
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	4.2

Notes:

[3] - Non-inferiority was assessed using a 2-sided exact 95% CI approach, with a non-inferiority margin of 4%.

Secondary: Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 96 as Determined by the FDA-Defined Snapshot Algorithm

End point title	Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 96 as Determined by the FDA-Defined Snapshot Algorithm
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End point description:

The percentage of participants achieving HIV-1 RNA < 50 copies/mL at Week 96 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

End point type	Secondary
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End point timeframe:

Week 96

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	280	276		
Units: percentage of participants				
number (not applicable)	82.1	88.4		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
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Statistical analysis description:

The analysis purpose of this efficacy endpoint was to assess the non-inferiority of switching to F/TAF+3rd Agent relative to maintaining treatment with ABC/3TC+3rd Agent. The difference in percentages and its 95% CI were calculated based on an unconditional exact method using 2 inverted 1-sided tests.

Comparison groups	F/TAF v ABC/3TC
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Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[4]
P-value	= 0.042
Method	Fisher exact
Parameter estimate	Difference in Percentages
Point estimate	-6.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.3
upper limit	-0.3

Notes:

[4] - Non-inferiority was assessed using a 2-sided exact 95% CI approach, with a non-inferiority margin of 4%.

Secondary: Percentage of Participants With HIV-1 RNA < 20 Copies/mL at Week 48 as Determined by the FDA-Defined Snapshot Algorithm

End point title	Percentage of Participants With HIV-1 RNA < 20 Copies/mL at Week 48 as Determined by the FDA-Defined Snapshot Algorithm
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End point description:

The percentage of participants achieving HIV-1 RNA < 20 copies/mL at Week 48 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

End point type	Secondary
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End point timeframe:

Week 48

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	280	276		
Units: percentage of participants				
number (not applicable)	85.7	87.3		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
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Statistical analysis description:

The analysis purpose of this efficacy endpoint was to assess the noninferiority of switching to F/TAF+3rd Agent relative to maintaining treatment with ABC/3TC+3rd Agent. The difference in percentages and its 95% CI were calculated based on an unconditional exact method using 2 inverted 1-sided tests.

Comparison groups	F/TAF v ABC/3TC
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Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
P-value	= 0.62
Method	Fisher exact
Parameter estimate	Difference in Percentages
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	4.2

Notes:

[5] - Non-inferiority was assessed using a 2-sided exact 95% CI approach, with a non-inferiority margin of 10%.

Secondary: Percentage of Participants With HIV-1 RNA < 20 Copies/mL at Week 96 as Determined by the FDA-Defined Snapshot Algorithm

End point title	Percentage of Participants With HIV-1 RNA < 20 Copies/mL at Week 96 as Determined by the FDA-Defined Snapshot Algorithm
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End point description:

The percentage of participants achieving HIV-1 RNA < 20 copies/mL at Week 96 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

End point type	Secondary
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End point timeframe:

Week 96

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	280	276		
Units: percentage of participants				
number (not applicable)	80.4	86.2		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
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Statistical analysis description:

The analysis purpose of this efficacy endpoint was to assess the noninferiority of switching to F/TAF+3rd Agent relative to maintaining treatment with ABC/3TC+3rd Agent. The difference in percentages and its 95% CI were calculated based on an unconditional exact method using 2 inverted 1-sided tests.

Comparison groups	F/TAF v ABC/3TC
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Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[6]
P-value	= 0.069
Method	Fisher exact
Parameter estimate	Difference in Percentages
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.2
upper limit	0.4

Notes:

[6] - Non-inferiority was assessed using a 2-sided exact 95% CI approach, with a non-inferiority margin of 10%.

Secondary: Change From Baseline in CD4 Cell Count at Week 48

End point title	Change From Baseline in CD4 Cell Count at Week 48
End point description:	
Participants in the Full Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe:	
Baseline; Week 48	

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	249	254		
Units: cells/ μ L				
arithmetic mean (standard deviation)	-30 ($\pm$ 152.3)	2 ($\pm$ 171.2)		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
Comparison groups	F/TAF v ABC/3TC
Number of subjects included in analysis	503
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.026 ^[7]
Method	ANOVA
Parameter estimate	Difference in LSM
Point estimate	-32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-61
upper limit	-4

Notes:

[7] - P-value, difference in least squares means (LSM), and its 95% CI were from ANOVA model with treatment and the third agent stratum (boosted protease inhibitors vs. others) as fixed effects in the model.

Secondary: Change From Baseline in CD4 Cell Count at Week 96

End point title	Change From Baseline in CD4 Cell Count at Week 96
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End point description:

Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary
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End point timeframe:

Baseline; Week 96

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	238		
Units: cells/ μ L				
arithmetic mean (standard deviation)	-29 ($\pm$ 160.7)	10 ($\pm$ 178.2)		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
Comparison groups	F/TAF v ABC/3TC
Number of subjects included in analysis	467
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013 ^[8]
Method	ANOVA
Parameter estimate	Difference in LSM
Point estimate	-39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-70
upper limit	-8

Notes:

[8] - P-value, difference in LSM, and its 95% CI were from ANOVA model with treatment and the 3rd agent stratum (boosted protease inhibitors vs. others) as fixed effects in the model.

Secondary: Percent Change From Baseline in Hip Bone Mineral Density (BMD) at Week 48

End point title	Percent Change From Baseline in Hip Bone Mineral Density (BMD) at Week 48
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End point description:

Participants in the Hip Dual-Energy X-Ray Absorptiometry (DXA) Analysis Set (all participants who are randomized and have received at least one dose of study drug, and have nonmissing baseline hip BMD values) with available data were analyzed.

End point type	Secondary
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End point timeframe:

Baseline; Week 48

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	231	236		
Units: percent change				
arithmetic mean (standard deviation)	0.246 ($\pm$ 2.2914)	0.086 ($\pm$ 2.3315)		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
Comparison groups	F/TAF v ABC/3TC
Number of subjects included in analysis	467
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4 ^[9]
Method	ANOVA
Parameter estimate	Difference in LSM
Point estimate	0.179
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	0.598

Notes:

[9] - P-value, difference in LSM, and its 95% CI were from ANOVA model with treatment and the 3rd agent stratum (boosted protease inhibitors vs. others) as fixed effects in the model.

Secondary: Percent Change From Baseline in Hip BMD at Week 96

End point title	Percent Change From Baseline in Hip BMD at Week 96
End point description:	
Participants in the Hip DXA Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe:	
Baseline; Week 96	

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	213	221		
Units: percent change				
arithmetic mean (standard deviation)	0.169 (± 2.7277)	0.021 (± 2.7212)		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
Comparison groups	F/TAF v ABC/3TC
Number of subjects included in analysis	434
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.53 ^[10]
Method	ANOVA
Parameter estimate	Difference in LSM
Point estimate	0.165
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.348
upper limit	0.678

Notes:

[10] - P-value, difference in LSM, and its 95% CI were from ANOVA model with treatment and the 3rd agent stratum (boosted protease inhibitors vs. others) as fixed effects in the model.

Secondary: Percent Change From Baseline in Spine BMD at Week 48

End point title	Percent Change From Baseline in Spine BMD at Week 48
End point description:	Participants in the Spine DXA Analysis Set (all participants who are randomized and have received at least one dose of study drug, and have nonmissing baseline spine BMD values) with available data were analyzed.
End point type	Secondary
End point timeframe:	
Baseline; Week 48	

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	232	240		
Units: percent change				
arithmetic mean (standard deviation)	0.081 (± 3.0051)	-0.052 (± 3.7550)		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
Comparison groups	F/TAF v ABC/3TC
Number of subjects included in analysis	472
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.63 ^[11]
Method	ANOVA
Parameter estimate	Difference in LSM
Point estimate	0.151
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.465
upper limit	0.767

Notes:

[11] - P-value, difference in LSM, and its 95% CI were from ANOVA model with treatment and the 3rd agent stratum (boosted protease inhibitors vs. others) as fixed effects in the model.

Secondary: Percent Change From Baseline in Spine BMD at Week 96

End point title	Percent Change From Baseline in Spine BMD at Week 96
End point description:	
Participants in the Spine DXA Analysis Set with available data were analyzed.	
End point type	Secondary
End point timeframe:	
Baseline; Week 96	

End point values	F/TAF	ABC/3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	217	225		
Units: percent change				
arithmetic mean (standard deviation)	0.178 (± 3.8881)	0.235 (± 4.3066)		

Statistical analyses

Statistical analysis title	Statistical Analysis - F/TAF vs ABC/3TC
Comparison groups	F/TAF v ABC/3TC
Number of subjects included in analysis	442
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.89 ^[12]
Method	ANOVA
Parameter estimate	Difference in LSM
Point estimate	-0.056

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.825
upper limit	0.713

Notes:

[12] - P-value, difference in LSM, and its 95% CI were from ANOVA model with treatment and the 3rd agent stratum (boosted protease inhibitors vs. others) as fixed effects in the model.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

First dose date to last dose date (maximum duration: 168 weeks) plus 30 days

Adverse event reporting additional description:

The Safety Analysis Set included all participants who were randomized and received at least 1 dose of study drug.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.1
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Reporting groups

Reporting group title	F/TAF (Double-Blind Phase)
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Reporting group description:

Adverse events reported occurred during the Double-Blind Phase in participants from the F/TAF group, who received F/TAF (200/10 mg) FDC tablet (with boosted 3rd ARV agent) or F/TAF (200/25 mg) FDC tablet (with unboosted 3rd ARV agent) + ABC/3TC placebo tablet once daily.

Reporting group title	ABC/3TC (Double-Blind Phase)
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Reporting group description:

Adverse events reported occurred during the Double-Blind Phase in participants from the ABC/3TC group, who received ABC/3TC (600/300 mg) FDC tablet + F/TAF placebo tablet once daily + allowed 3rd ARV agent.

Reporting group title	Open-Label F/TAF From F/TAF
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Reporting group description:

Adverse events reported occurred during the Open-Label Extension Phase in participants who enrolled into the Open-Label Extension Phase from the F/TAF group and received F/TAF (200/10 mg or 200/25 mg) FDC tablet once daily.

Reporting group title	Open-Label F/TAF From ABC/3TC
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Reporting group description:

Adverse events reported occurred during the Open-Label Extension Phase in participants who enrolled into the Open-Label Extension Phase from the ABC/3TC group and received F/TAF (200/10 mg or 200/25 mg) FDC tablet once daily.

Serious adverse events	F/TAF (Double-Blind Phase)	ABC/3TC (Double-Blind Phase)	Open-Label F/TAF From F/TAF
Total subjects affected by serious adverse events			
subjects affected / exposed	55 / 280 (19.64%)	32 / 276 (11.59%)	0 / 6 (0.00%)
number of deaths (all causes)	5	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hodgkin's disease			
subjects affected / exposed	2 / 280 (0.71%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung cancer metastatic			

subjects affected / exposed	1 / 280 (0.36%)	1 / 276 (0.36%)	0 / 6 (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
Acute myeloid leukaemia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Anal cancer			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Anogenital warts			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Choroid melanoma			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Colon cancer			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Ganglioneuroma			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Ovarian cancer metastatic			

subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Prostate cancer			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Rectal cancer			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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			
Deep vein thrombosis			
subjects affected / exposed	2 / 280 (0.71%)	3 / 276 (1.09%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	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	2 / 280 (0.71%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Death			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Sudden cardiac death			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Social circumstances			
Substance use			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 280 (0.00%)	3 / 276 (1.09%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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			
Suicide attempt			
subjects affected / exposed	2 / 280 (0.71%)	1 / 276 (0.36%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	1 / 280 (0.36%)	1 / 276 (0.36%)	0 / 6 (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
Alcohol abuse			

subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Bipolar disorder			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Depression			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Drug abuse			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Intentional self-injury			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Schizophrenia			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Substance abuse			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Transaminases increased			

subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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 load increased			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Femur fracture			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Fibula fracture			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Poisoning			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Road traffic accident			

subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Seroma			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine perforation			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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			
Coronary artery disease			
subjects affected / exposed	1 / 280 (0.36%)	1 / 276 (0.36%)	0 / 6 (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
Myocardial infarction			
subjects affected / exposed	1 / 280 (0.36%)	1 / 276 (0.36%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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 failure congestive			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Cardio-respiratory arrest			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Coronary artery stenosis			

subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Pericarditis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Cerebral infarction			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Epilepsy			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Hydrocephalus			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Loss of consciousness			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Metabolic encephalopathy			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Presyncope			

subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Seizure			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Transient ischaemic attack			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Leukocytosis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Neutropenia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 280 (0.36%)	1 / 276 (0.36%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Faecaloma			

subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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 haemorrhage			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Haematemesis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Ileus paralytic			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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 ischaemia			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Large intestine perforation			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Oesophageal ulcer			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Pancreatitis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Pancreatitis acute			

subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Rectal haemorrhage			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Umbilical hernia			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 280 (1.07%)	0 / 276 (0.00%)	0 / 6 (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
Nephrolithiasis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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 colic			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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			
Intervertebral disc protrusion			
subjects affected / exposed	1 / 280 (0.36%)	1 / 276 (0.36%)	0 / 6 (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

Osteonecrosis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Pathological fracture			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	5 / 280 (1.79%)	2 / 276 (0.72%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 280 (0.36%)	2 / 276 (0.72%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 280 (0.36%)	1 / 276 (0.36%)	0 / 6 (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
Gastroenteritis			
subjects affected / exposed	0 / 280 (0.00%)	2 / 276 (0.72%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			

subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Abscess neck			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Acute hepatitis C			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Clostridium difficile infection			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Dengue fever			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Diarrhoea infectious			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Escherichia pyelonephritis			

subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Groin abscess			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Herpes zoster oticus			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Oesophageal candidiasis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Peritonitis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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 legionella			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Postoperative wound infection			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Respiratory tract infection			

subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Staphylococcal abscess			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Staphylococcal infection			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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 myocarditis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 280 (0.71%)	0 / 276 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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
Diabetic ketoacidosis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 276 (0.00%)	0 / 6 (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
Hyponatraemia			
subjects affected / exposed	0 / 280 (0.00%)	1 / 276 (0.36%)	0 / 6 (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

Serious adverse events	Open-Label F/TAF		
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	From ABC/3TC		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hodgkin's disease			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung cancer metastatic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute myeloid leukaemia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal cancer			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anogenital warts			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Choroid melanoma			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Colon cancer			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ganglioneuroma			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer metastatic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			
subjects affected / exposed	0 / 5 (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	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Asthenia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sudden cardiac death			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Substance use			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Suicide attempt			

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychotic disorder				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Alcohol abuse				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bipolar disorder				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug abuse				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intentional self-injury				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Schizophrenia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Substance abuse				

subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transaminases increased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral load increased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femoral neck fracture			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fibula fracture			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Meniscus injury				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Poisoning				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seroma				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine perforation				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Coronary artery disease				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				

subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 5 (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 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Faecaloma				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematemesis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus paralytic				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal ulcer				

subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal colic			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pathological fracture			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhabdomyolysis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Appendicitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal wall abscess				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess neck				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute hepatitis C				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dengue fever				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea infectious				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia pyelonephritis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin abscess				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster oticus				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal candidiasis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia legionella				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				

subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal abscess			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral myocarditis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 5 (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	F/TAF (Double-Blind Phase)	ABC/3TC (Double-Blind Phase)	Open-Label F/TAF From F/TAF
Total subjects affected by non-serious adverse events			
subjects affected / exposed	190 / 280 (67.86%)	199 / 276 (72.10%)	1 / 6 (16.67%)
Vascular disorders			
Hypertension			
subjects affected / exposed	15 / 280 (5.36%)	15 / 276 (5.43%)	0 / 6 (0.00%)
occurrences (all)	15	15	0
Nervous system disorders			
Headache			
subjects affected / exposed	31 / 280 (11.07%)	25 / 276 (9.06%)	0 / 6 (0.00%)
occurrences (all)	35	36	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	21 / 280 (7.50%)	15 / 276 (5.43%)	0 / 6 (0.00%)
occurrences (all)	22	16	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	30 / 280 (10.71%)	37 / 276 (13.41%)	0 / 6 (0.00%)
occurrences (all)	38	43	0
Nausea			
subjects affected / exposed	14 / 280 (5.00%)	11 / 276 (3.99%)	0 / 6 (0.00%)
occurrences (all)	15	11	0
Vomiting			
subjects affected / exposed	14 / 280 (5.00%)	10 / 276 (3.62%)	0 / 6 (0.00%)
occurrences (all)	16	10	0
Respiratory, thoracic and mediastinal			

disorders Cough subjects affected / exposed occurrences (all)	34 / 280 (12.14%) 41	30 / 276 (10.87%) 40	0 / 6 (0.00%) 0
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	14 / 280 (5.00%) 14	17 / 276 (6.16%) 19	0 / 6 (0.00%) 0
Renal and urinary disorders Renal colic subjects affected / exposed occurrences (all)	1 / 280 (0.36%) 1	0 / 276 (0.00%) 0	0 / 6 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all) Musculoskeletal pain subjects affected / exposed occurrences (all) Spinal pain subjects affected / exposed occurrences (all)	28 / 280 (10.00%) 31 24 / 280 (8.57%) 26 22 / 280 (7.86%) 22 11 / 280 (3.93%) 11 0 / 280 (0.00%) 0	29 / 276 (10.51%) 29 31 / 276 (11.23%) 32 15 / 276 (5.43%) 18 14 / 276 (5.07%) 15 1 / 276 (0.36%) 1	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 1 / 6 (16.67%) 1
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Bronchitis	57 / 280 (20.36%) 80 36 / 280 (12.86%) 53	49 / 276 (17.75%) 76 46 / 276 (16.67%) 63	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0

subjects affected / exposed	19 / 280 (6.79%)	14 / 276 (5.07%)	0 / 6 (0.00%)
occurrences (all)	23	16	0
Urinary tract infection			
subjects affected / exposed	13 / 280 (4.64%)	18 / 276 (6.52%)	0 / 6 (0.00%)
occurrences (all)	18	30	0
Influenza			
subjects affected / exposed	12 / 280 (4.29%)	15 / 276 (5.43%)	0 / 6 (0.00%)
occurrences (all)	14	16	0
Gastroenteritis			
subjects affected / exposed	11 / 280 (3.93%)	15 / 276 (5.43%)	0 / 6 (0.00%)
occurrences (all)	12	17	0
Syphilis			
subjects affected / exposed	15 / 280 (5.36%)	5 / 276 (1.81%)	0 / 6 (0.00%)
occurrences (all)	16	5	0
Rhinitis			
subjects affected / exposed	7 / 280 (2.50%)	6 / 276 (2.17%)	0 / 6 (0.00%)
occurrences (all)	8	6	0

Non-serious adverse events	Open-Label F/TAF From ABC/3TC		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Spinal pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		

Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Bronchitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Influenza subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Syphilis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Rhinitis subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		

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

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/29475804>

<http://www.ncbi.nlm.nih.gov/pubmed/30932951>