Clinical trial results:
A Phase IIIb, randomized, open-label study of the safety and efficacy of dolutegravir/abacavir/lamivudine once daily compared to atazanavir and ritonavir plus tenofovir/emtricitabine once daily in HIV-1 infected antiretroviral therapy naïve women

Summary

EudraCT number	2012-005823-34
Trial protocol	GB IT ES PT FR
Global end of trial date	18 August 2022

Results information

Result version number	v2 (current)
This version publication date	02 August 2023
First version publication date	10 August 2016
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	117172

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01910402
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ViiV Healthcare
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS
Public contact	GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.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	21 October 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 August 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferior antiviral activity of DTG/ABC/3TC FDC once daily compared to atazanavir (ATV) + Ritonavir (RTV) + tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) FDC each administered once daily over 48 weeks in Human Immunodeficiency Virus Type 1 (HIV-1) infected Antiretroviral Therapy (ART) naïve women

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 August 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Russian Federation: 50
Country: Number of subjects enrolled	South Africa: 66
Country: Number of subjects enrolled	Argentina: 44
Country: Number of subjects enrolled	Thailand: 40
Country: Number of subjects enrolled	Italy: 28
Country: Number of subjects enrolled	Spain: 54
Country: Number of subjects enrolled	United States: 134
Country: Number of subjects enrolled	United Kingdom: 25
Country: Number of subjects enrolled	Mexico: 11
Country: Number of subjects enrolled	Canada: 20
Country: Number of subjects enrolled	France: 16
Country: Number of subjects enrolled	Portugal: 9
Country: Number of subjects enrolled	Puerto Rico: 2
Worldwide total number of subjects	499
EEA total number of subjects	107

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)	493
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study consists of a Screening (14-28 days), Randomized (48 weeks) and Continuation (Cont.) Phase. Participants were said to have completed the study if they completed the Randomized phase and did not enter the Cont. Phase. Participants entering the Cont. Phase were said to have completed the study if they completed both phases of the study.

Pre-assignment

Screening details:

A total of 499 participants were randomized to receive DTG/ABC/3TC FDC or combination of ATV+RTV+TDF/FTC. Two from each DTG/ABC/3TC and ATV+RTV+TDF/FTC groups were randomized but not treated. A total of 495 participants received at least single dose of investigational products(IP) and were included in Intent-to-Treat Exposed(ITT-E) Population.

Period 1

Period 1 title	Randomized phase (Up to 48 weeks)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase

Arm description:

Participants received fixed dose combination (FDC) of DTG 50 milligram (mg)/ABC 600 mg/3TC 300 mg tablet once daily orally for 48 weeks in the Randomization Phase.

Arm type	Experimental
Investigational medicinal product name	Dolutegravir (DTG)/ Abacavir (ABC)/ Lamivudine (3TC) fixed dose combination (FDC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received FDC of DTG 50 mg/ABC 600 mg/3TC 300 mg tablet once daily orally

Arm title	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase

Arm description:

Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF 300 mg/ FTC 200 mg FDC tablet once daily orally for 48 weeks during Randomized Phase.

Arm type	Active comparator
Investigational medicinal product name	Atazanavir (ATV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received ATV 300 mg capsule once daily

Investigational medicinal product name	Tenofovir disoproxil fumarate/Emtricitabine (TDF/FTC) FDC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:	
Participants received FDC of TDF 300 mg/ FTC 200 mg tablet once daily	
Investigational medicinal product name	Ritonavir (RTV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received RTV 100 mg tablet once daily

Number of subjects in period 1[1]	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Started	248	247
Completed	206	192
Not completed	42	55
Physician decision	1	-
Consent withdrawn by subject	5	7
Adverse event, non-fatal	10	18
Protocol Deviation	10	13
Lost to follow-up	11	13
Lack of efficacy	5	4

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: A total of 499 participants were randomized to receive DTG/ABC/3TC FDC or combination of ATV+RTV+TDF/FTC. Two from each DTG/ABC/3TC and ATV+RTV+TDF/FTC groups were randomized but not treated. A total of 495 participants received at least single dose of investigational products(IP) and were included in Intent-to-Treat Exposed(ITT-E) Population.

Period 2

Period 2 title	Continuation Phase(From Weeks 48 to 432)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase

Arm description:

Participants received DTG 50 mg/ABC 600 mg/3TC 300 mg once daily orally in the Continuation Phase until it was either locally approved or commercial supplies were available.

Arm type	Experimental
Investigational medicinal product name	Dolutegravir (DTG)/ Abacavir (ABC)/ Lamivudine (3TC) fixed dose combination (FDC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received FDC of DTG 50 mg/ABC 600 mg/3TC 300 mg tablet once daily orally

Number of subjects in period 2[2]	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase
Started	149
Completed	113
Not completed	36
Adverse event, serious fatal	1
Physician decision	1
Consent withdrawn by subject	7
Adverse event, non-fatal	3
Protocol Deviation	15
Lost to follow-up	8
Lack of efficacy	1

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: 149 entered from Randomized to Continuation Phase

Baseline characteristics

Reporting groups	
Reporting group title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase
Reporting group description:	
Participants received fixed dose combination (FDC) of DTG 50 milligram (mg)/ABC 600 mg/3TC 300 mg tablet once daily orally for 48 weeks in the Randomization Phase.	
Reporting group title	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Reporting group description:	
Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF 300 mg/ FTC 200 mg FDC tablet once daily orally for 48 weeks during Randomized Phase.	

Reporting group values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase	Total
Number of subjects	248	247	495
Age categorical			
Units: Participants			
Age continuous			
Units: years			
arithmetic mean	38.1	37.8	
standard deviation	± 11.15	± 10.14	-
Gender categorical			
Units: Participants			
Female	248	247	495
Male	0	0	0
Race/Ethnicity, Customized			
Units: Subjects			
African American/African Heritage	102	108	210
American Indian Or Alaskan Native	6	7	13
Asian - Central/South Asian Heritage	2	0	2
Asian - East Asian Heritage	0	1	1
Asian - South East Asian Heritage	20	22	42
Native Hawaiian Or Other Pacific Islander	1	0	1
White - Arabic/North African Heritage	3	3	6
White - White/Caucasian/European Heritage	112	104	216
Mixed Race	2	2	4

End points

End points reporting groups

Reporting group title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase

Reporting group description:

Participants received fixed dose combination (FDC) of DTG 50 milligram (mg)/ABC 600 mg/3TC 300 mg tablet once daily orally for 48 weeks in the Randomization Phase.

Reporting group title	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase

Reporting group description:

Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF 300 mg/ FTC 200 mg FDC tablet once daily orally for 48 weeks during Randomized Phase.

Reporting group title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase

Reporting group description:

Participants received DTG 50 mg/ABC 600 mg/3TC 300 mg once daily orally in the Continuation Phase until it was either locally approved or commercial supplies were available.

Subject analysis set title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received fixed dose combination (FDC) of DTG/ABC/3TC 50 milligram (mg)/600 mg/300 mg tablet once daily orally for 48 weeks in the Randomization Phase. Participants who completed 48 weeks of treatment, continued to receive DTG/ABC/3TC in the Continuation Phase until it was either locally approved or commercial supplies were available.

Subject analysis set title	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200mg QD
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF/FTC FDC 300 mg/200 mg tablet once daily orally for 48 weeks during Randomized Phase

Subject analysis set title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received fixed dose combination (FDC) of DTG/ABC/3TC 50 milligram (mg)/600 mg/300 mg tablet once daily orally for 48 weeks in the Randomization Phase. Participants who completed 48 weeks of treatment, continued to receive DTG/ABC/3TC in the Continuation Phase until it was either locally approved or commercial supplies were available.

Subject analysis set title	ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200mg QD
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF/FTC FDC 300 mg/200 mg tablet once daily orally for 48 weeks during Randomized Phase

Primary: Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48

End point title	Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48

End point description:

Percentage of participants with plasma human immunodeficiency virus type 1(HIV-1) ribonucleic acid (RNA) <50 copies per milliliter (c/mL) were assessed at Week 48 using the Snapshot algorithm. Analysis was performed using a stratified analysis with Cochran-Mantel-Haenszel (CMH) weights, adjusting for Baseline plasma HIV-1 RNA (=<vs. >100,000 c/mL) and CD4+ cell count (=<350 cells per millimeter cube (cells/mm^3) or >350 cells/mm^3). Intent-to-Treat Exposed (ITT-E) Population comprised of all randomized participants who received at least one dose of study medication. Percentage values are rounded off.

End point type	Primary

End point timeframe:

Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[1]	247[2]		
Units: Percentage of participants	82	71		

Notes:

[1] - ITT-E Population.

[2] - ITT-E Population.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Hypothesis was to show that the antiviral effect of the DTG/ABC/3TC FDC administered QD was non-inferior to QD ATV+RTV+TDF/FTC FDC. Non-inferiority was concluded if the lower bound of a two-sided 95% confidence interval for the difference in response rates between the two treatment arms was greater than -12%

Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.005 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted difference in proportion
Point estimate	10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	17.8

Notes:

[3] - If the primary and PP analyses both demonstrated non-inferiority, then as per pre-specified analysis, superiority of DTG/ABC/3TC FDC versus ATV+RTV+TDF/FTC FDC was tested in the ITT-E population at the 2-sided 5% level of significance.

Secondary: Percentage of participants with plasma HIV-1 RNA <50 and <400 c/mL over time-Randomized Phase

End point title	Percentage of participants with plasma HIV-1 RNA <50 and <400 c/mL over time-Randomized Phase

End point description:

Percentage of participants with plasma HIV-1 RNA <50 and <400 c/mL were assessed at Baseline, Weeks 4, 12, 24 , 36 and 48 using the Snapshot algorithm (Missing, Switch or Discontinuation = Failure). The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Percentage values are rounded off.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[4]	247[5]		
Units: Percentage of participants				
HIV-1 RNA <50 c/mL, Baseline (Day 1)	0	0		
HIV-1 RNA <50 c/mL, Week 4	64	13		
HIV-1 RNA <50 c/mL, Week 12	81	49		
HIV-1 RNA <50 c/mL, Week 24	85	77		
HIV-1 RNA <50 c/mL, Week 36	85	77		
HIV-1 RNA <50 c/mL, Week 48	82	71		
HIV-1 RNA <400 c/mL, Baseline (Day 1)	1	1		
HIV-1 RNA <400 c/mL, Week 4	90	54		
HIV-1 RNA <400 c/mL, Week 12	91	84		
HIV-1 RNA <400 c/mL, Week 24	88	82		
HIV-1 RNA <400 c/mL, Week 36	86	81		
HIV-1 RNA <400 c/mL, Week 48	83	76		

Notes:

[4] - ITT-E Population

[5] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <50 c/mL in Continuation Phase

End point title	Percentage of participants with plasma HIV-1 RNA <50 c/mL in Continuation Phase

End point description:

Plasma samples were collected for quantitative analysis of HIV-1 RNA. Percentage of participants with plasma HIV-1 RNA <50 c/mL were reported. Percentage values are rounded off. Only those participants with data available at indicated time points were analyzed (represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Week 96 and Week 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	149[6]			
Units: Percentage of participants				
Week 96, n=99	100			
Week 432, n=3	100			

Notes:

[6] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Plasma HIV-1 RNA at indicated time points-Randomized Phase

End point title	Change from Baseline in Plasma HIV-1 RNA at indicated time points-Randomized Phase

End point description:

Change from the Baseline in plasma HIV-1 RNA were assessed at indicated time points. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at indicated time points were analyzed (represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[7]	247[8]		
Units: Log10 copies/mL				
arithmetic mean (standard deviation)				
Week 4, n=245, 238	-2.591 (± 0.8015)	-1.923 (± 0.5330)		
Week 12, n=236, 226	-2.756 (± 0.8920)	-2.541 (± 0.7373)		
Week 24, n=225, 212	-2.789 (± 0.9160)	-2.726 (± 0.8890)		
Week 36, n=221, 204	-2.838 (± 0.8589)	-2.772 (± 0.8451)		
Week 48, n=207, 192	-2.874 (± 0.8035)	-2.752 (± 0.8433)		

Notes:

[7] - ITT-E Population

[8] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values in Plasma HIV-1 RNA at indicated time points-Randomized Phase

End point title	Absolute Values in Plasma HIV-1 RNA at indicated time points-Randomized Phase

End point description:

Absolute Values in plasma HIV-1 RNA were assessed at indicated time points. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Only those participants with data available at indicated time points were analyzed (represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[9]	247[10]		
Units: Log10 copies/mL				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=248, 247	4.481 (± 0.8111)	4.441 (± 0.8023)		
Week 4, n=245, 238	1.895 (± 0.6872)	2.516 (± 0.6193)		
Week 12, n=236, 226	1.748 (± 0.5458)	1.908 (± 0.4926)		
Week 24, n=225, 212	1.724 (± 0.5935)	1.710 (± 0.4484)		
Week 36, n=221, 204	1.666 (± 0.3982)	1.658 (± 0.3362)		
Week 48, n=207, 192	1.619 (± 0.1986)	1.657 (± 0.2743)		

Notes:

[9] - ITT-E Population

[10] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Plasma HIV-1 RNA at indicated time points-Continuation Phase

End point title	Change from Baseline in Plasma HIV-1 RNA at indicated time points-Continuation Phase

End point description:

Change from the Baseline in plasma HIV-1 RNA were assessed at indicated time points. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at indicated time points were analyzed (represented by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 96 and Week 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	149[11]			
Units: Log10 copies/mL				
arithmetic mean (standard deviation)				
Week 96, n=99	-2.911 (± 0.7970)			
Week 432, n=3	-3.107 (± 0.7659)			

Notes:

[11] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in CD4+ cell count at indicated timepoints-Randomized Phase

End point title	Change from Baseline in CD4+ cell count at indicated timepoints-Randomized Phase

End point description:

Change from Baseline in cluster of differentiation 4 (CD4+) cell count were assessed at indicated time points. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at indicated time points were analyzed (represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[12]	247[13]		
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)				
Week 4, n=245, 237	94.9 (± 140.02)	73.7 (± 108.15)		
Week 12, n=236, 224	143.8 (± 142.19)	124.4 (± 133.60)		
Week 24, n=226, 210	200.6 (± 162.37)	163.0 (± 126.67)		
Week 36, n=219, 204	230.7 (± 163.61)	191.4 (± 167.24)		
Week 48, n=208, 191	248.8 (± 172.01)	230.7 (± 189.59)		

Notes:

[12] - ITT-E Population

[13] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values in Plasma HIV-1 RNA at indicated time points-Continuation Phase

End point title	Absolute Values in Plasma HIV-1 RNA at indicated time points-Continuation Phase

End point description:

Absolute Values in plasma HIV-1 RNA were assessed at indicated time points. Only those participants with data available at indicated time points were analyzed (represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Week 96 and Week 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	149[14]			
Units: Log10 copies/mL				
arithmetic mean (standard deviation)				
Week 96, n=99	1.591 (± 0.0080)			
Week 432, n=3	1.590 (± 0.0000)			

Notes:

[14] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values in CD4+ cell count at indicated timepoints-Randomized Phase

End point title	Absolute values in CD4+ cell count at indicated timepoints-Randomized Phase

End point description:

Absolute values in CD4+ cell count were assessed at indicated time points. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Only those participants with data available at indicated time points were analyzed (represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[15]	247[16]		
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=248, 247	369.7 (± 225.67)	380.3 (± 223.60)		
Week 4, n=245, 237	465.0 (± 252.51)	455.1 (± 244.62)		
Week 12, n=236, 224	509.5 (± 276.79)	506.2 (± 266.84)		
Week 24, n=226, 210	563.8 (± 303.10)	542.5 (± 265.69)		
Week 36, n=219, 204	592.8 (± 291.62)	569.2 (± 299.77)		
Week 48, n=208, 191	608.8 (± 298.95)	608.5 (± 302.58)		

Notes:

[15] - ITT-E Population

[16] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in CD4+ cell count at indicated timepoints-Continuation Phase

End point title	Change from Baseline in CD4+ cell count at indicated timepoints-Continuation Phase

End point description:

Change from Baseline in cluster of differentiation 4(CD4+) cell count were assessed at indicated time points. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at indicated time points were analyzed (represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 96, Week 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	149[17]			
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)				
Week 96, n=99	286.5 (± 196.77)			
Week 432, n=3	254.7 (± 342.31)			

Notes:

[17] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values in CD4+ cell count at indicated timepoints-Continuation Phase

End point title	Absolute values in CD4+ cell count at indicated timepoints-Continuation Phase

End point description:

Absolute values in CD4+ cell count were assessed at indicated time points. Only those participants with data available at indicated time points were analyzed (represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Week 96 and Week 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	149[18]			
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)				
Week 96, n=99	635.3 (± 285.85)			
Week 432, n=3	553.0 (± 341.63)			

Notes:

[18] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in carbon dioxide, electrolytes, lipids, glucose, urea at indicated time points

End point title	Change from Baseline in carbon dioxide, electrolytes, lipids, glucose, urea at indicated time points

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Weeks 4, 12, 24, 36 and 48. Change from Baseline in carbon dioxide, electrolytes (chloride, hyperkalemia, hypernatremia, hypokalemia, hyponatremia, phosphate, potassium, sodium), lipids (cholesterol [CHLS], high density lipoprotein [HDL] CHLS direct, low density lipoprotein (LDL) CHLS calculation, LDL CHLS direct, triglycerides), glucose (hyperglycaemia, hypoglycaemia) and urea are summarized. Baseline value was defined as the latest pre-dose assessment(Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Laboratory parameters were assessed in Safety Population which comprised of all participants who received at least one dose of study treatment. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles). 99999 indicates standard deviation could not be calculated for a single participant

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[19]	247[20]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Carbon Dioxide, Week 4, n= 244, 237	-0.4 (± 2.29)	0.6 (± 2.2)		
Carbon Dioxide, Week 12, n= 236, 226	-0.2 (± 2.2)	0.8 (± 2.19)		
Carbon Dioxide, Week 24, n= 224, 212	-0.5 (± 2.31)	0.3 (± 2.38)		
Carbon Dioxide, Week 36, n= 219, 204	0 (± 2.34)	0.6 (± 2.5)		

Carbon Dioxide, Week 48, n= 208, 192	-0.6 (± 2.55)	0.4 (± 2.46)		
Chloride, Week 4, n= 245, 237	0.6 (± 2.42)	-0.5 (± 2.68)		
Chloride, Week 12, n= 236, 226	1 (± 2.51)	0.2 (± 2.58)		
Chloride, Week 24, n= 225, 212	0.7 (± 2.71)	-0.1 (± 2.58)		
Chloride, Week 36, n= 219, 204	0.9 (± 2.65)	0 (± 2.96)		
Chloride, Week 48, n= 208, 192	0.7 (± 2.42)	0 (± 2.63)		
CHLS, Week 4, n= 1, 3	-0.1 (± 99999)	-0.017 (± 0.446)		
CHLS, Week 12, n= 224, 221	0.298 (± 0.7492)	-0.058 (± 0.7137)		
CHLS, Week 24, n= 218, 201	0.317 (± 0.7254)	-0.001 (± 0.7456)		
CHLS, Week 36, n= 205, 191	0.33 (± 0.7328)	0 (± 0.7509)		
CHLS, Week 48, n= 195, 175	0.447 (± 0.7441)	0.109 (± 0.7647)		
Glucose, Week 12, n= 226, 224	0.3 (± 1.359)	0.22 (± 1.234)		
Glucose, Week 24, n= 219, 204	0.17 (± 0.811)	0.26 (± 1.248)		
Glucose, Week 36, n= 211, 196	0.17 (± 1.24)	0.34 (± 1.753)		
Glucose, Week 48, n= 197, 180	0.18 (± 1.01)	0.24 (± 1.377)		
HDL CHLS, Direct, Week 4, n= 1, 3	-0.1 (± 99999)	0 (± 0.0529)		
HDL CHLS, Direct, Week 12, n= 224, 221	0.182 (± 0.3407)	0.005 (± 0.2316)		
HDL CHLS, Direct, Week 24, n= 218, 201	0.201 (± 0.2962)	0.053 (± 0.2819)		
HDL CHLS, Direct, Week 36, n= 205, 191	0.204 (± 0.2943)	0.036 (± 0.2848)		
HDL CHLS, Direct, Week 48, n= 195, 175	0.231 (± 0.2911)	0.081 (± 0.2964)		
Hyperglycaemia, Week 12, n= 226, 224	0.3 (± 1.359)	0.22 (± 1.234)		
Hyperglycaemia, Week 24, n= 219, 204	0.17 (± 0.811)	0.26 (± 1.248)		
Hyperglycaemia, Week 36, n= 211, 196	0.17 (± 1.24)	0.34 (± 1.753)		
Hyperglycaemia, Week 48, n= 197, 180	0.18 (± 1.01)	0.24 (± 1.377)		
Hyperkalemia, Week 4, n= 244, 237	-0.01 (± 0.344)	0.12 (± 0.367)		
Hyperkalemia, Week 12, n= 236, 226	0.03 (± 0.355)	0.1 (± 0.39)		
Hyperkalemia, Week 24, n= 224, 212	-0.04 (± 0.339)	0.06 (± 0.372)		
Hyperkalemia, Week 36, n= 219, 204	0.03 (± 0.332)	0.13 (± 0.387)		
Hyperkalemia, Week 48, n= 208, 192	-0.04 (± 0.346)	0.04 (± 0.372)		
Hypernatremia, Week 4, n= 245, 237	0 (± 2.11)	-0.5 (± 2.4)		
Hypernatremia, Week 12, n= 236, 226	0.7 (± 2.3)	0.1 (± 2.51)		
Hypernatremia, Week 24, n= 225, 212	0.6 (± 2.3)	0.2 (± 2.11)		
Hypernatremia, Week 36, n= 219, 204	0.9 (± 2.32)	0.2 (± 2.5)		
Hypernatremia, Week 48, n= 208, 192	0.6 (± 2.24)	0.5 (± 2.39)		
Hypoglycaemia, Week 12, n= 226, 224	0.3 (± 1.359)	0.22 (± 1.234)		
Hypoglycaemia, Week 24, n= 219, 204	0.17 (± 0.811)	0.26 (± 1.248)		
Hypoglycaemia, Week 36, n= 211, 196	0.17 (± 1.24)	0.34 (± 1.753)		
Hypoglycaemia, Week 48, n= 197, 180	0.18 (± 1.01)	0.24 (± 1.377)		
Hypokalemia, Week 4, n= 244, 237	-0.01 (± 0.344)	0.12 (± 0.367)		
Hypokalemia, Week 12, n= 236, 226	0.03 (± 0.355)	0.1 (± 0.39)		
Hypokalemia, Week 24, n= 224, 212	-0.04 (± 0.339)	0.06 (± 0.372)		
Hypokalemia, Week 36, n= 219, 204	0.03 (± 0.332)	0.13 (± 0.387)		

Hypokalemia, Week 48, n= 208, 192	-0.04 (± 0.346)	0.04 (± 0.372)		
Hyponatremia, Week 4, n= 245, 237	0 (± 2.11)	-0.5 (± 2.4)		
Hyponatremia, Week 12, n= 236, 226	0.7 (± 2.3)	0.1 (± 2.51)		
Hyponatremia, Week 24, n= 225, 212	0.6 (± 2.3)	0.2 (± 2.11)		
Hyponatremia, Week 36, n= 219, 204	0.9 (± 2.32)	0.2 (± 2.5)		
Hyponatremia, Week 48, n= 208, 192	0.6 (± 2.24)	0.5 (± 2.39)		
LDL CHLS Calculation, Week 4, n= 1, 3	0.08 (± 99999)	-0.123 (± 0.5255)		
LDL CHLS Calculation, Week 12, n= 221, 219	0.125 (± 0.6045)	-0.14 (± 0.6114)		
LDL CHLS Calculation, Week 24, n= 213, 201	0.111 (± 0.6209)	-0.111 (± 0.6188)		
LDL CHLS Calculation, Week 36, n= 201, 188	0.112 (± 0.6385)	-0.099 (± 0.6049)		
LDL CHLS Calculation, Week 48, n= 190, 175	0.213 (± 0.6499)	-0.021 (± 0.6227)		
LDL CHLS, Direct, Week 12, n= 0, 1	88888 (± 88888)	-0.44 (± 99999)		
LDL CHLS, Direct, Week 24, n= 1, 0	-0.64 (± 99999)	88888 (± 88888)		
LDL CHLS, Direct, Week 36, n= 1, 0	-0.23 (± 99999)	88888 (± 88888)		
LDL CHLS, Direct, Week 48, n= 0, 0	88888 (± 88888)	88888 (± 88888)		
Phosphate, Week 4, n= 245, 237	0 (± 0.1461)	-0.032 (± 0.1726)		
Phosphate, Week 12, n= 236, 226	0.02 (± 0.1694)	0.026 (± 0.1634)		
Phosphate, Week 24, n= 225, 212	0.021 (± 0.1628)	0.026 (± 0.1701)		
Phosphate, Week 36, n= 219, 204	0.029 (± 0.1736)	0.009 (± 0.1675)		
Phosphate, Week 48, n= 208, 192	0.016 (± 0.1736)	0 (± 0.1673)		
Potassium, Week 4, n= 244, 237	-0.01 (± 0.344)	0.12 (± 0.367)		
Potassium, Week 12, n= 236, 226	0.03 (± 0.355)	0.1 (± 0.39)		
Potassium, Week 24, n= 224, 212	-0.04 (± 0.339)	0.06 (± 0.372)		
Potassium, Week 36, n= 219, 204	0.03 (± 0.332)	0.13 (± 0.387)		
Potassium, Week 48, n= 208, 192	-0.04 (± 0.346)	0.04 (± 0.372)		
Sodium, Week 4, n= 245, 237	0 (± 2.11)	-0.5 (± 2.4)		
Sodium, Week 12, n= 236, 226	0.7 (± 2.3)	0.1 (± 2.51)		
Sodium, Week 24, n= 225, 212	0.6 (± 2.3)	0.2 (± 2.11)		
Sodium, Week 36, n= 219, 204	0.9 (± 2.32)	0.2 (± 2.5)		
Sodium, Week 48, n= 208, 192	0.6 (± 2.24)	0.5 (± 2.39)		
Triglycerides, Week 4, n= 1, 3	-0.18 (± 99999)	0.237 (± 0.2491)		
Triglycerides, Week 12, n= 224, 221	-0.04 (± 0.6861)	0.167 (± 0.7074)		
Triglycerides, Week 24, n= 218, 201	0.036 (± 0.7108)	0.125 (± 0.6132)		
Triglycerides, Week 36, n= 205, 191	0.037 (± 0.6732)	0.157 (± 0.6785)		
Triglycerides, Week 48, n= 195, 175	0.018 (± 0.8158)	0.107 (± 0.5527)		
Urea, Week 4, n= 245, 237	-0.04 (± 1.085)	0.1 (± 1.313)		

Urea, Week 12, n= 236, 226	0.08 (± 1.097)	0.16 (± 1.409)		
Urea, Week 24, n= 225, 212	0.03 (± 1.187)	0.12 (± 1.283)		
Urea, Week 36, n= 219, 204	0.08 (± 1.236)	-0.03 (± 1.256)		
Urea, Week 48, n= 208, 192	0.1 (± 1.162)	0.02 (± 1.179)		

Notes:

[19] - Safety Population

[20] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in bilirubin and creatinine at indicated timepoints

End point title	Change from Baseline in bilirubin and creatinine at indicated timepoints

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Weeks 4, 12, 24, 36 and 48. Change from Baseline in bilirubin and creatinine are summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[21]	247[22]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin, Week 4, n= 244, 237	-0.8 (± 2.59)	27.2 (± 23.15)		
Bilirubin, Week 12, n= 236, 226	-0.6 (± 2.65)	22.8 (± 16.49)		
Bilirubin, Week 24, n= 225, 212	-0.2 (± 3.06)	25 (± 18.38)		
Bilirubin, Week 36, n= 219, 204	-0.2 (± 3.01)	23.8 (± 16.31)		
Bilirubin, Week 48, n= 208, 192	-0.3 (± 3.08)	23.7 (± 17)		
Creatinine, Week 4, n= 245, 237	8.4 (± 7.057)	4.89 (± 7.109)		
Creatinine, Week 12, n= 236, 226	9.2 (± 8.288)	5.83 (± 8.357)		
Creatinine, Week 24, n= 225, 212	9.16 (± 9.983)	5.8 (± 8.063)		
Creatinine, Week 36, n= 219, 204	10.08 (± 10.473)	5.37 (± 9.013)		
Creatinine, Week 48, n= 208, 192	9.29 (± 8.614)	5.86 (± 10.252)		

Notes:

[21] - Safety Population

[22] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in albumin at indicated timepoints

End point title	Change from Baseline in albumin at indicated timepoints

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in albumin is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[23]	247[24]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Week 4, n= 245, 237	0.1 (± 2.36)	-0.5 (± 2.59)		
Week 12, n= 236, 226	0.5 (± 2.95)	0.1 (± 2.59)		
Week 24, n= 225, 212	1.4 (± 3.2)	0.8 (± 2.95)		
Week 36, n= 219, 204	1.4 (± 3.09)	0.6 (± 2.96)		
Week 48, n= 208, 192	1.7 (± 3.17)	1.3 (± 3.04)		

Notes:

[23] - Safety Population

[24] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, creatine kinase at indicated time points

End point title	Change from Baseline in alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, creatine kinase at indicated time points

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, creatine kinase is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value.Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:
Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[25]	247[26]		
Units: International units per liter				
arithmetic mean (standard deviation)				
Alanine aminotransferase, Week 4, n= 245, 237	-3.3 (± 27.54)	-3.4 (± 15.86)		
Alanine aminotransferase, Week 12, n= 236, 226	-5.2 (± 27.51)	-2.3 (± 20.26)		
Alanine aminotransferase, Week 24, n= 225, 212	-5.4 (± 27.92)	-3.7 (± 20.7)		
Alanine aminotransferase, Week 36, n= 219, 204	-4.9 (± 36.11)	-5.3 (± 20.08)		
Alanine aminotransferase, Week 48, n= 208, 192	-5.7 (± 28.54)	-1.5 (± 31.53)		
Alkaline phosphatase, Week 4, n= 245, 237	-1.5 (± 14.56)	9.4 (± 28.69)		
Alkaline phosphatase, Week 12, n= 236, 226	-2.1 (± 17.1)	15.1 (± 30.82)		
Alkaline phosphatase, Week 24, n= 225, 212	0.5 (± 17.86)	22.4 (± 41.59)		
Alkaline phosphatase, Week 36, n= 219, 204	0.6 (± 19.19)	20.4 (± 30.7)		
Alkaline phosphatase, Week 48, n= 208, 192	2.9 (± 28.05)	21.9 (± 25.35)		
Aspartate aminotransferase, Week 4, n= 244, 237	-3.3 (± 29.8)	-3.6 (± 18.83)		
Aspartate aminotransferase, Week 12, n= 236, 226	-6.2 (± 21.11)	-4 (± 13.79)		
Aspartate aminotransferase, Week 24, n= 224, 212	-6.3 (± 22.44)	-5.1 (± 13.8)		
Aspartate aminotransferase, Week 36, n= 219, 204	-6.4 (± 31.42)	-6.5 (± 16.63)		
Aspartate aminotransferase, Week 48, n= 208, 192	-7.5 (± 22.19)	-3.7 (± 25.28)		
Creatine Kinase, Week 4, n= 245, 237	-0.3 (± 68.72)	35.6 (± 549.1)		
Creatine Kinase, Week 12, n= 236, 226	6.9 (± 73.7)	7.3 (± 90.39)		
Creatine Kinase, Week 24, n= 225, 212	10.3 (± 88.66)	5.8 (± 77.12)		
Creatine Kinase, Week 36, n= 219, 204	11.9 (± 155.68)	7.2 (± 132.74)		
Creatine Kinase, Week 48, n= 208, 192	23.8 (± 242.66)	3.8 (± 98.58)		

Notes:
[25] - Safety Population
[26] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in creatinine clearance at indicated time points

End point title	Change from Baseline in creatinine clearance at indicated time points

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in creatinine clearance is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[27]	247[28]		
Units: Milliliter per minute				
arithmetic mean (standard deviation)				
Week 4, n= 245, 237	-16.3 (± 15.03)	-7.5 (± 12.91)		
Week 12, n= 236, 226	-17.3 (± 17.01)	-7 (± 23.14)		
Week 24, n= 225, 212	-16.2 (± 20.36)	-9.1 (± 16.88)		
Week 36, n= 219, 204	-16.8 (± 22.35)	-7.5 (± 17.67)		
Week 48, n= 208, 192	-15.9 (± 19.62)	-7.7 (± 18.42)		

Notes:

[27] - Safety Population

[28] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in lipase at indicated timepoints

End point title	Change from Baseline in lipase at indicated timepoints

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in lipase is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[29]	247[30]		
Units: Units per liter				
arithmetic mean (standard deviation)				
Week 4, n= 245, 237	-1.2 (± 15.06)	-1.3 (± 15.81)		
Week 12, n= 236, 226	-2.2 (± 22.74)	-2.1 (± 29)		
Week 24, n= 225, 212	-6 (± 21.05)	-6 (± 18.57)		
Week 36, n= 219, 204	-6.3 (± 25.62)	-6.3 (± 21.36)		
Week 48, n= 208, 192	-6.5 (± 29.63)	-7.8 (± 20.72)		

Notes:

[29] - Safety Population

[30] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in total CHLS/HDL CHLS ratio at indicated timepoints

End point title	Change from Baseline in total CHLS/HDL CHLS ratio at indicated timepoints

End point description:

Clinical chemistry parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in Total CHLS/HDL CHLS ratio is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles). 99999 indicates standard deviation could not be calculated for a single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[31]	247[32]		

Units: Ratio				
arithmetic mean (standard deviation)				
Week 4, n= 1, 4	0.1264 (± 99999)	0.2159 (± 0.60727)		
Week 12, n= 233, 223	-0.2736 (± 1.0283)	-0.1092 (± 0.73776)		
Week 24, n= 224, 209	-0.3098 (± 1.11093)	-0.1922 (± 0.79848)		
Week 36, n= 212, 198	-0.3286 (± 1.01181)	-0.1433 (± 0.79498)		
Week 48, n= 207, 186	-0.2886 (± 1.01415)	-0.1444 (± 1.23362)		

Notes:

[31] - Safety Population

[32] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in basophils, eosinophils, lymphocytes, monocytes at indicated time points

End point title	Change from Baseline in basophils, eosinophils, lymphocytes, monocytes at indicated time points

End point description:

Hematology parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in basophils, eosinophils, lymphocytes, monocytes is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[33]	247[34]		
Units: 10^9 cells per liter				
arithmetic mean (standard deviation)				
Basophils, Week 4, n= 241, 234	0.003 (± 0.0182)	0.003 (± 0.0198)		
Basophils, Week 12, n= 228, 216	0.002 (± 0.0174)	0.003 (± 0.0162)		
Basophils, Week 24, n= 221, 208	0.004 (± 0.0187)	0.003 (± 0.0155)		
Basophils, Week 36, n= 214, 203	0.004 (± 0.0182)	0.003 (± 0.0158)		
Basophils, Week 48, n= 206, 189	0.005 (± 0.0199)	0.006 (± 0.0146)		

Eosinophils, Week 4, n= 241, 234	0.040 (± 0.1486)	0.021 (± 0.1648)		
Eosinophils, Week 12, n= 228, 216	0.037 (± 0.1982)	-0.001 (± 0.1610)		
Eosinophils, Week 24, n= 221, 208	0.028 (± 0.1927)	0.005 (± 0.1973)		
Eosinophils, Week 36, n= 214, 203	0.048 (± 0.2244)	0.014 (± 0.2139)		
Eosinophils, Week 48, n= 206, 189	0.030 (± 0.1744)	0.007 (± 0.2274)		
Lymphocytes, Week 4, n= 241, 234	0.208 (± 0.4914)	0.119 (± 0.5493)		
Lymphocytes, Week 12, n= 228, 216	0.257 (± 0.5500)	0.156 (± 0.6690)		
Lymphocytes, Week 24, n= 221, 208	0.317 (± 0.4889)	0.192 (± 0.5910)		
Lymphocytes, Week 36, n= 214, 203	0.362 (± 0.5199)	0.178 (± 0.6441)		
Lymphocytes, Week 48, n= 206, 189	0.359 (± 0.5235)	0.261 (± 0.7098)		
Monocytes, Week 4, n= 241, 234	-0.001 (± 0.1558)	-0.015 (± 0.1391)		
Monocytes, Week 12, n= 228, 216	-0.010 (± 0.1412)	-0.031 (± 0.1369)		
Monocytes, Week 24, n= 221, 208	0.008 (± 0.1498)	-0.015 (± 0.1581)		
Monocytes, Week 36, n= 214, 203	-0.006 (± 0.1448)	-0.028 (± 0.1500)		
Monocytes, Week 48, n= 206, 189	0.001 (± 0.1379)	-0.024 (± 0.1638)		

Notes:

[33] - Safety Population

[34] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in erythrocytes at indicated time points

End point title	Change from Baseline in erythrocytes at indicated time points

End point description:

Hematology parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in erythrocytes is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[35]	247[36]		
Units: 10^12 cells per liter				
arithmetic mean (standard deviation)				
Week 4, n= 243, 234	-0.04 (± 0.244)	-0.07 (± 0.239)		
Week 12, n= 233, 220	-0.07 (± 0.351)	-0.09 (± 0.308)		
Week 24, n= 225, 211	-0.08 (± 0.373)	-0.09 (± 0.329)		
Week 36, n= 218, 203	-0.10 (± 0.384)	-0.08 (± 0.358)		
Week 48, n= 207, 190	-0.10 (± 0.365)	-0.05 (± 0.318)		

Notes:

[35] - Safety Population

[36] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in erythrocyte mean corpuscular volume at indicated time points

End point title	Change from Baseline in erythrocyte mean corpuscular volume at indicated time points

End point description:

Hematology parameters were assessed at Baseline (Day 1), Week 4, 12, 24, 36 and Week 48. Change from Baseline in erythrocyte mean corpuscular volume (EMCV) is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[37]	247[38]		
Units: Femtoliter				
arithmetic mean (standard deviation)				
Week 4, n= 243, 234	0.9 (± 1.81)	0.5 (± 1.83)		
Week 12, n= 233, 220	3.4 (± 2.98)	1.9 (± 2.94)		

Week 24, n= 225, 211	5.5 (± 4.03)	3.1 (± 4.33)		
Week 36, n= 218, 203	6.0 (± 4.04)	3.1 (± 5.22)		
Week 48, n= 207, 190	7.1 (± 4.31)	3.7 (± 5.15)		

Notes:

[37] - Safety Population

[38] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematocrit count at indicated time points

End point title	Change from Baseline in hematocrit count at indicated time points

End point description:

Hematology parameters were assessed at Baseline (Day 1), Weeks 4, 12, 24, 36 and 48. Change from Baseline in hematocrit is summarized. Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 12, Week 24, Week 36 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[39]	247[40]		
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Week 4, n= 243, 234	0.0003 (± 0.02176)	-0.0042 (± 0.02238)		
Week 12, n= 233, 220	0.0081 (± 0.03157)	0.0000 (± 0.02646)		
Week 24, n= 225, 211	0.0157 (± 0.03209)	0.0051 (± 0.03083)		
Week 36, n= 218, 203	0.0167 (± 0.03451)	0.0062 (± 0.03379)		
Week 48, n= 207, 190	0.0212 (± 0.03293)	0.0107 (± 0.03200)		

Notes:

[39] - Safety Population

[40] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Triglycerides at Week 48

End point title	Change from Baseline in Triglycerides at Week 48

End point description:

Change from Baseline in mean triglycerides at Week 48. Baseline value defined as latest pre-dose assessment(Day1) value. Change from Baseline calculated as post-dose visit minus Baseline value. Adjusted mean is estimated mean change from Baseline in fasted triglycerides at Week48 in each arm calculated from a model adjusted for following covariates: treatment, Baseline plasma HIV-1 RNA, CD4+ cell count, age and triglycerides. Participants on lipid lowering therapy at Baseline excluded from analysis. Measurements collected after a participant initiates lipid lowering therapy were set to missing. Missing values imputed using multiple imputation under a multivariate normal model adjusting for Baseline plasma HIV-1 RNA, Baseline CD4+ cell count, fasted triglycerides and TC/HDL ratio at Baseline, Week12 and Week36. Participants on lipid lowering therapy at Baseline excluded from analysis. Only those participants with data available at specified time points were analyzed

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	226[41]	214[42]		
Units: Millimoles per liter				
least squares mean (standard error)	0.045 (± 0.0477)	0.070 (± 0.0477)		

Notes:

[41] - Safety Population

[42] - Safety Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	440
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7053
Method	Multiple Imputed Dataset - MAR
Parameter estimate	Mean difference (final values)
Point estimate	-0.026
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.159
upper limit	0.107

Secondary: Change from Baseline in urine albumin creatinine ratio at indicated time points

End point title	Change from Baseline in urine albumin creatinine ratio at indicated time points

End point description:

Change from Baseline in urine albumin creatinine ratio at Week 24 and Week 48 is summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 24 and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[43]	247[44]		
Units: milligrams per millimole				
arithmetic mean (standard deviation)				
Week 24, n= 179, 186	-1.15 (± 16.557)	-1.03 (± 9.091)		
Week 48, n= 170, 164	-0.68 (± 20.597)	-0.10 (± 9.393)		

Notes:

[43] - Safety Population

[44] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With AEs by maximum toxicity-Randomized Phase

End point title	Number of Participants With AEs by maximum toxicity-Randomized Phase

End point description:

Number of participants with Grade 1-4 AEs by maximum toxicity were assessed from the start of study treatment and until end of the Randomization phase. AEs are categorized into following grades as per The Division of Aqcuired Immuno Deficiency Syndrome (AIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table)- Grade 1- mild, Grade 2- moderate; Grade 3- severe and Grade 4- potentially life-threatening. Higher the grade, more severe the symptoms.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[45]	247[46]		
Units: Participants				
Grade 1	79	60		
Grade 2	94	91		
Grade 3	18	37		
Grade 4	3	9		

Notes:

[45] - Safety Population

[46] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in total cholesterol (TC)/HDL Ratio at Week 48

End point title	Change from Baseline in total cholesterol (TC)/HDL Ratio at Week 48

End point description:

Change from Baseline in mean TC/HDL ratio at Week48. Baseline value defined as latest pre-dose assessment(Day1) value. Change from Baseline calculated as post-dose visit minus Baseline value. Adjusted mean is estimated mean change from Baseline in fasted TC/HDL at Week48 in each arm calculated from a model adjusted for following covariates: treatment, Baseline plasma HIV-1 RNA, CD4+ cell count, age and TC/HDL. Participants on lipid lowering therapy at Baseline excluded from analysis. Measurements collected after a participant initiates lipid lowering therapy were set to missing. Missing values were imputed using multiple imputation under a multivariate normal model adjusting for Baseline plasma HIV-1 RNA, Baseline CD4+ cell count, fasted triglycerides and TC/HDL ratio at Baseline, Week12 and Week36. Participants on lipid lowering therapy at Baseline excluded from analysis. Only those participants with data available at specified time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	226[47]	214[48]		
Units: Ratio				
least squares mean (standard error)	-0.264 (± 0.0707)	-0.158 (± 0.0784)		

Notes:

[47] - Safety Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	440
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3165
Method	Multiple Imputed Dataset - MAR
Parameter estimate	Mean difference (final values)
Point estimate	-0.106
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.313
upper limit	0.101

Secondary: Number of participants with any adverse events (AEs), and serious adverse events (SAEs)-Randomized Phase

End point title	Number of participants with any adverse events (AEs), and serious adverse events (SAEs)-Randomized Phase

End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. An SAE is any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect or other events that may jeopardize the participant or may require medical or surgical intervention to prevent one of the outcome listed above, liver injury and impaired liver function and grade 4 laboratory abnormalities. Number of participants with any AEs, and SAEs have been presented.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[49]	247[50]		
Units: Participants				
Any AEs	195	197		
Any SAEs	12	20		

Notes:

[49] - Safety Population

[50] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With AEs by maximum toxicity-Continuation Phase

End point title	Number of Participants With AEs by maximum toxicity-Continuation Phase

End point description:

Number of participants with Grade 1-4 AEs were assessed in Continuation Phase. AEs are categorized into following grades as per The Division of Aqcuired Immuno Deficiency Syndrome (AIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table)- Grade 1- mild, Grade 2- moderate; Grade 3- severe and Grade 4- potentially life-threatening. Higher the grade, more severe the symptoms. Safety - Continuation Phase Population comprised of all participants in the DTG/ABC/3TC group who received at least 1 dose of study treatment after entering the Continuation Phase.

End point type	Secondary

End point timeframe:

From Weeks 48 to 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	149[51]			
Units: Participants				
Grade 1	32			
Grade 2	48			
Grade 3	7			
Grade 4	6			

Notes:

[51] - Safety - Continuation Phase Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any AEs, and SAEs in Continuation Phase

End point title	Number of participants with any AEs, and SAEs in Continuation Phase

End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. An SAE is any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect or other events that may jeopardize the participant or may require medical or surgical intervention to prevent one of the outcome listed above, liver injury and impaired liver function and grade 4 laboratory abnormalities. Number of participants with any AEs, and SAEs have been presented.

End point type	Secondary

End point timeframe:

From Weeks 48 to 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	149[52]			
Units: Participants				
Any AEs	93			
Any SAEs	13			

Notes:

[52] - Safety-Continuation Phase Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with maximum post-Baseline emergent chemistry toxicities-Randomized Phase

End point title	Number of Participants with maximum post-Baseline emergent chemistry toxicities-Randomized Phase

End point description:

Number of participants with Grade 1-4 emergent chemistry toxicities were assessed from the start of study treatment and end of Randomized Phase. Chemistry toxicities were categorized into following grades as per The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table)- Grade 1- mild, Grade 2- moderate; Grade 3- severe and Grade 4- potentially life-threatening. Higher the grade, more severe the symptoms. Data has been reported for clinical chemistry parameters including hyperglycaemia, hyperkalemia, hypernatremia, hypoglycaemia, hypokalemia, hyponatremia, alanine aminotransferase, albumin, alkaline phosphatase, aspartate aminotransferase, bilirubin, carbon dioxide, cholesterol, creatine kinase, creatinine, LDL cholesterol calculation, LDL cholesterol direct, lipase, phosphate, potassium, sodium, triglycerides and glucose.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[53]	247[54]		
Units: Participants				
Hyperglycaemia, Grade 1	17	11		
Hyperglycaemia, Grade 2	16	9		
Hyperglycaemia, Grade 3	4	3		
Hyperglycaemia, Grade 4	1	0		
Hyperkalemia, Grade 1	1	0		
Hyperkalemia, Grade 2	0	1		
Hyperkalemia, Grade 3	0	0		
Hyperkalemia, Grade 4	0	0		
Hypernatremia, Grade 1	1	0		
Hypernatremia, Grade 2	0	0		
Hypernatremia, Grade 3	0	0		
Hypernatremia, Grade 4	0	0		
Hypoglycaemia, Grade 1	6	5		
Hypoglycaemia, Grade 2	3	1		
Hypoglycaemia, Grade 3	1	0		
Hypoglycaemia, Grade 4	0	0		
Hypokalemia, Grade 1	17	19		
Hypokalemia, Grade 2	1	0		
Hypokalemia, Grade 3	0	0		
Hypokalemia, Grade 4	0	0		
Hyponatremia, Grade 1	44	57		
Hyponatremia, Grade 2	1	0		
Hyponatremia, Grade 3	0	0		
Hyponatremia, Grade 4	0	0		
Alanine aminotransferase, Grade 1	5	7		
Alanine aminotransferase, Grade 2	6	4		
Alanine aminotransferase, Grade 3	1	2		
Alanine aminotransferase, Grade 4	1	0		
Albumin, Grade 1	3	2		
Albumin, Grade 2	0	2		
Albumin, Grade 3	0	0		
Albumin, Grade 4	0	0		
Alkaline phosphatase, Grade 1	3	14		
Alkaline phosphatase, Grade 2	2	1		
Alkaline phosphatase, Grade 3	0	0		
Alkaline phosphatase, Grade 4	0	0		
Aspartate aminotransferase, Grade 1	12	7		
Aspartate aminotransferase, Grade 2	4	4		
Aspartate aminotransferase, Grade 3	1	2		
Aspartate aminotransferase, Grade 4	1	0		
Bilirubin, Grade 1	2	52		
Bilirubin, Grade 2	0	86		
Bilirubin, Grade 3	0	57		

Bilirubin, Grade 4	0	5		
Carbon dioxide, Grade 1	65	54		
Carbon dioxide, Grade 2	4	3		
Carbon dioxide, Grade 3	0	0		
Carbon dioxide, Grade 4	0	0		
Cholesterol, Grade 1	52	31		
Cholesterol, Grade 2	28	9		
Cholesterol, Grade 3	4	2		
Cholesterol, Grade 4	0	0		
Creatine kinase, Grade 1	3	5		
Creatine kinase, Grade 2	1	1		
Creatine kinase, Grade 3	3	0		
Creatine kinase, Grade 4	0	1		
Creatinine, Grade 1	3	7		
Creatinine, Grade 2	0	3		
Creatinine, Grade 3	1	0		
Creatinine, Grade 4	0	0		
LDL cholesterol calculation, Grade 1	38	21		
LDL cholesterol calculation, Grade 2	13	9		
LDL cholesterol calculation, Grade 3	7	2		
LDL cholesterol calculation, Grade 4	0	0		
LDL cholesterol direct, Grade 1	3	1		
LDL cholesterol direct, Grade 2	1	0		
LDL cholesterol direct, Grade 3	0	0		
LDL cholesterol direct, Grade 4	0	0		
Lipase, Grade 1	12	7		
Lipase, Grade 2	5	3		
Lipase, Grade 3	3	2		
Lipase, Grade 4	0	1		
Phosphate, Grade 1	5	11		
Phosphate, Grade 2	7	9		
Phosphate, Grade 3	1	2		
Phosphate, Grade 4	0	0		
Potassium, Grade 1	18	19		
Potassium, Grade 2	1	1		
Potassium, Grade 3	0	0		
Potassium, Grade 4	0	0		
Sodium, Grade 1	45	57		
Sodium, Grade 2	1	0		
Sodium, Grade 3	0	0		
Sodium, Grade 4	0	0		
Triglycerides, Grade 1	0	0		
Triglycerides, Grade 2	5	2		
Triglycerides, Grade 3	2	0		
Triglycerides, Grade 4	0	0		
Glucose, Grade 1	22	15		
Glucose, Grade 2	19	10		
Glucose, Grade 3	4	3		
Glucose, Grade 4	1	0		

Notes:
[53] - Safety Population
[54] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With maximum post-Baseline emergent chemistry toxicities-Continuation Phase

End point title	Number of Participants With maximum post-Baseline emergent chemistry toxicities-Continuation Phase

End point description:

Number of participants with Grade1-4 emergent chemistry toxicities were assessed in Continuation Phase. Chemistry toxicities categorized into following grades as per The Division of AIDS Table for Grading Severity of Adult and Pediatric Adverse Events(DAIDS AE Grading Table)-Grade 1-mild, Grade 2-moderate;Grade 3-severe and Grade 4-potentially life-threatening. Higher the grade, more severe the symptoms. Data has been reported for clinical chemistry parameters including hyperglycaemia, hypernatremia, hypoglycaemia, hypokalemia, hyponatremia, alanine aminotransferase, albumin, alkaline phosphatase, aspartate aminotransferase, bilirubin, carbon dioxide, cholesterol, creatine kinase, creatinine, LDL cholesterol calculation, LDL cholesterol direct, lipase, phosphate, potassium, sodium, triglycerides and glucose. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

From Weeks 48 to 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	149[55]			
Units: Participants				
Hyperglycaemia, Grade 1, n=143	24			
Hyperglycaemia, Grade 2, n=143	9			
Hyperglycaemia, Grade 3, n=143	3			
Hyperglycaemia, Grade 4, n=143	0			
Hypernatremia, Grade 1, n=146	2			
Hypernatremia, Grade 2, n=146	0			
Hypernatremia, Grade 3, n=146	0			
Hypernatremia, Grade 4, n=146	0			
Hypoglycaemia, Grade 1, n=143	1			
Hypoglycaemia, Grade 2, n=143	0			
Hypoglycaemia, Grade 3, n=143	0			
Hypoglycaemia, Grade 4, n=143	1			
Hypokalemia, Grade 1, n=146	13			
Hypokalemia, Grade 2, n=146	0			
Hypokalemia, Grade 3, n=146	0			

Hypokalemia, Grade 4, n=146	0			
Hyponatremia, Grade 1, n=146	36			
Hyponatremia, Grade 2, n=146	0			
Hyponatremia, Grade 3, n=146	0			
Hyponatremia, Grade 4, n=146	0			
Alanine aminotransferase, Grade 1, n=146	7			
Alanine aminotransferase, Grade 2, n=146	3			
Alanine aminotransferase, Grade 3, n=146	0			
Alanine aminotransferase, Grade 4, n=146	2			
Alkaline phosphatase, Grade 1, n=146	5			
Alkaline phosphatase, Grade 2, n=146	0			
Alkaline phosphatase, Grade 3, n=146	0			
Alkaline phosphatase, Grade 4, n=146	0			
Aspartate aminotransferase, Grade 1, n=146	10			
Aspartate aminotransferase, Grade 2, n=146	2			
Aspartate aminotransferase, Grade 3, n=146	0			
Aspartate aminotransferase, Grade 4, n=146	2			
Bilirubin, Grade 1, n=146	4			
Bilirubin, Grade 2, n=146	1			
Bilirubin, Grade 3, n=146	3			
Bilirubin, Grade 4, n=146	0			
Carbon dioxide, Grade 1, n=146	58			
Carbon dioxide, Grade 2, n=146	7			
Carbon dioxide, Grade 3, n=146	0			
Carbon dioxide, Grade 4, n=146	0			
Cholesterol, Grade 1, n=71	9			
Cholesterol, Grade 2, n=71	9			
Cholesterol, Grade 3, n=71	3			
Cholesterol, Grade 4, n=71	0			
Creatine kinase, Grade 1, n=146	6			
Creatine kinase, Grade 2, n=146	1			
Creatine kinase, Grade 3, n=146	1			
Creatine kinase, Grade 4, n=146	1			
Creatinine, Grade 1, n=146	5			
Creatinine, Grade 2, n=146	0			
Creatinine, Grade 3, n=146	0			
Creatinine, Grade 4, n=146	1			
LDL cholesterol calculation, Grade 1, n=70	5			
LDL cholesterol calculation, Grade 2, n=70	8			
LDL cholesterol calculation, Grade 3, n=70	2			
LDL cholesterol calculation, Grade 4, n=70	0			
LDL cholesterol direct, Grade 1, n=2	1			
LDL cholesterol direct, Grade 2, n=2	0			
LDL cholesterol direct, Grade 3, n=2	0			

LDL cholesterol direct, Grade 4, n=2	0			
Lipase, Grade 1, n=146	9			
Lipase, Grade 2, n=146	6			
Lipase, Grade 3, n=146	1			
Lipase, Grade 4, n=146	1			
Phosphate, Grade 1, n=146	2			
Phosphate, Grade 2, n=146	15			
Phosphate, Grade 3, n=146	2			
Phosphate, Grade 4, n=146	0			
Potassium, Grade 1, n=146	13			
Potassium, Grade 2, n=146	0			
Potassium, Grade 3, n=146	0			
Potassium, Grade 4, n=146	0			
Sodium, Grade 1, n=146	37			
Sodium, Grade 2, n=146	0			
Sodium, Grade 3, n=146	0			
Sodium, Grade 4, n=146	0			
Triglycerides, Grade 1, n=71	0			
Triglycerides, Grade 2, n=71	1			
Triglycerides, Grade 3, n=71	0			
Triglycerides, Grade 4, n=71	0			
Glucose, Grade 1, n=143	24			
Glucose, Grade 2, n=143	9			
Glucose, Grade 3, n=143	3			
Glucose, Grade 4, n=143	1			

Notes:

[55] - Safety-Continuation Phase Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with maximum post-Baseline emergent hematology toxicities-Randomized Phase

End point title	Number of Participants with maximum post-Baseline emergent hematology toxicities-Randomized Phase

End point description:

Number of participants with Grade 1-4 emergent hematology toxicities were assessed from the start of study treatment and end of Randomized Phase. Hematology toxicities were categorized into following grades as per The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table)- Grade 1- mild, Grade 2- moderate; Grade 3- severe and Grade 4- potentially life-threatening. Higher the grade, more severe the symptoms. Data has been reported for clinical chemistry parameters including hemoglobin, leukocytes, neutrophils and platelets.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[56]	247[57]		
Units: Participants				
Hemoglobin, Grade 1	7	21		
Hemoglobin, Grade 2	2	3		
Hemoglobin, Grade 3	1	1		
Hemoglobin, Grade 4	0	0		
Leukocytes, Grade 1	5	6		
Leukocytes, Grade 2	1	2		
Leukocytes, Grade 3	0	0		
Leukocytes, Grade 4	0	0		
Neutrophils, Grade 1	15	12		
Neutrophils, Grade 2	7	9		
Neutrophils, Grade 3	0	2		
Neutrophils, Grade 4	1	1		
Platelets, Grade 1	6	1		
Platelets, Grade 2	0	2		
Platelets, Grade 3	1	0		
Platelets, Grade 4	0	0		

Notes:

[56] - Safety Population

[57] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With maximum post-Baseline emergent hematology toxicities-Continuation Phase

End point title	Number of Participants With maximum post-Baseline emergent hematology toxicities-Continuation Phase

End point description:

Number of participants with Grade 1-4 emergent hematology toxicities were assessed in Continuation Phase. Hematology toxicities were categorized into following grades as per The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table)- Grade 1-mild, Grade 2- moderate; Grade 3- severe and Grade 4- potentially life-threatening. Higher the grade, more severe the symptoms. Data has been reported for clinical chemistry parameters including hemoglobin, leukocytes, neutrophils and platelets. Only those participants with data available at specified time points were analyzed.

End point type	Secondary

End point timeframe:

From Weeks 48 to 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	146[58]			
Units: Participants				
Hemoglobin, Grade 1	5			
Hemoglobin, Grade 2	1			
Hemoglobin, Grade 3	0			
Hemoglobin, Grade 4	0			
Leukocytes, Grade 1	2			
Leukocytes, Grade 2	0			
Leukocytes, Grade 3	1			
Leukocytes, Grade 4	0			
Neutrophils, Grade 1	10			
Neutrophils, Grade 2	2			
Neutrophils, Grade 3	1			
Neutrophils, Grade 4	1			
Platelets, Grade 1	3			
Platelets, Grade 2	1			
Platelets, Grade 3	0			
Platelets, Grade 4	0			

Notes:

[58] - Safety - Continuation Phase Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who withdrew from treatment due to AEs-Continuation phase

End point title	Number of participants who withdrew from treatment due to AEs-Continuation phase

End point description:

An AE is defined as any untoward medical occurrence in a participant temporally associated with the use of a medicinal product (MP), whether or not considered related to the MP. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of an MP. An SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, is an important medical event that jeopardizes the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition, or is associated with liver injury and impaired liver function.

End point type	Secondary

End point timeframe:

From Weeks 48 to 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase			
Subject group type	Reporting group			
Number of subjects analysed	149[59]			
Units: Participants	4			

Notes:

[59] - Safety - Continuation Phase Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who withdrew from treatment due to AEs-Randomized Phase

End point title	Number of participants who withdrew from treatment due to AEs-Randomized Phase

End point description:

An AE is defined as any untoward medical occurrence in a participant temporally associated with the use of a medicinal product (MP), whether or not considered related to the MP. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of an MP. An SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, is an important medical event that jeopardizes the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition, or is associated with liver injury and impaired liver function.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[60]	247[61]		
Units: Participants	10	17		

Notes:

[60] - Safety Population

[61] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in bone specific alkaline phosphatase, osteocalcin and procollagen 1 N-terminal propeptide at indicated timepoints

End point title	Change from Baseline in bone specific alkaline phosphatase, osteocalcin and procollagen 1 N-terminal propeptide at indicated timepoints

End point description:

Bone markers were assessed at Baseline (Day 1), Weeks 24, 48. Change from Baseline in bone specific alkaline phosphatase (BSAP), osteocalcin and procollagen 1 N-terminal propeptide (PTP) is summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Weeks 24 and 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[62]	247[63]		
Units: Micrograms per liter				
arithmetic mean (standard deviation)				
BSAP, Week 24, n=219, 207	1.33 (± 3.934)	6.00 (± 5.962)		
BSAP, Week 48, n=202, 184	2.64 (± 5.746)	7.60 (± 7.144)		
Osteocalcin, Week 24, n=209, 197	3.73 (± 7.484)	14.38 (± 22.205)		
Osteocalcin, Week 48, n=194, 178	5.15 (± 9.018)	16.30 (± 25.043)		
PTP, Week 24, n=223, 206	10.1 (± 20.11)	32.0 (± 27.89)		
PTP, Week 48, n=205, 186	11.2 (± 23.05)	34.1 (± 27.28)		

Notes:

[62] - Safety Population

[63] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Type I collagen C-telopeptides at indicated timepoints

End point title	Change from Baseline in Type I collagen C-telopeptides at indicated timepoints

End point description:

Bone markers were assessed at Baseline (Day 1), Weeks 24, 48. Change from Baseline in Type I collagen C-telopeptides (T-1 CCT) is summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Weeks 24 and 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[64]	247[65]		
Units: Nanograms per liter				
arithmetic mean (standard deviation)				
Week 24, n=221, 207	89.8 (± 173.09)	272.4 (± 205.22)		
Week 48, n=202, 185	75.9 (± 173.73)	267.9 (± 200.82)		

Notes:

[64] - Safety Population

[65] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in vitamin D, vitamin D2 and vitamin D3 at Week 24 and Week 48

End point title	Change from Baseline in vitamin D, vitamin D2 and vitamin D3 at Week 24 and Week 48

End point description:

Bone markers were assessed at Baseline (Day 1), Weeks 24, 48. Change from Baseline in vitamin D, vitamin D2 and vitamin D3 is summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1), Weeks 24 and 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[66]	247[67]		
Units: Nanomoles per liter				
arithmetic mean (standard deviation)				
Vitamin D, Week 24, n=223, 208	1.8 (± 24.95)	16.3 (± 31.66)		
Vitamin D, Week 48, n=206, 186	-1.9 (± 20.63)	8.9 (± 23.78)		
Vitamin D2, Week 24, n=223, 208	0.3 (± 6.04)	1.0 (± 7.88)		

Vitamin D2, Week 48, n=206, 186	0.1 (± 4.71)	0.9 (± 11.00)		
Vitamin D3, Week 24, n=223, 208	1.5 (± 24.33)	15.2 (± 31.39)		
Vitamin D3, Week 48, n=206, 186	-1.9 (± 20.56)	7.9 (± 21.72)		

Notes:

[66] - Safety Population

[67] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Bone specific alkaline phosphatase, osteocalcin, procollagen 1 N-terminal propeptide, Type 1 Collagen C-Telopeptide, vitamin D ratio of Week 48 results over Baseline

End point title	Bone specific alkaline phosphatase, osteocalcin, procollagen 1 N-terminal propeptide, Type 1 Collagen C-Telopeptide, vitamin D ratio of Week 48 results over Baseline

End point description:

Bone markers assessed at indicated timepoints. Bone specific alkaline phosphatase(BSAP), osteocalcin and procollagen 1 N-terminal propeptide(PTP), Type 1 Collagen C-Telopeptide, vitaminD ratio of Week48 results over Baseline is calculated. Bone biomarkers analyzed based on log transformed data. Estimates of adjusted mean and difference calculated from an Analysis of covariance(ANCOVA) model adjusting for age, baseline viral load Baseline CD4+ cell count, Baseline biomarker level, body mass index category, smoking status and baseline Vitamin D use. Adjusted mean of log-transformed change from Baseline transformed back to Week48/Baseline ratio for each treatment group. Adjusted difference of log-transformed change from Baseline between treatment groups is transformed back to ratio of Week48/Baseline ratio in DTG/ABC/3TC FDC to ATV+RTV+TDF/FTC FDC. Only those participants with data available at specified time points were analyzed(represented by n=X in category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[68]	247[69]		
Units: Ratio				
number (confidence interval 95%)				
BSAP, n=202, 183	1.188 (1.135 to 1.243)	1.629 (1.553 to 1.708)		
PTP, n=202, 184	1.214 (1.158 to 1.272)	1.752 (1.668 to 1.840)		
Osteocalcin, n=194, 178	1.282 (1.214 to 1.354)	2.039 (1.926 to 2.159)		
Type 1 Collagen C-Telopeptide, n=202, 184	1.257 (1.195 to 1.323)	1.918 (1.819 to 2.023)		
Vitamin D, n=206, 186	0.987 (0.940 to 1.036)	1.158 (1.101 to 1.219)		

Notes:
[68] - Safety Population
[69] - Safety Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: BSAP ratio of Week 48 result over Baseline	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio of ratios
Point estimate	0.729
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.683
upper limit	0.779

Statistical analysis title	Statistical Analysis 5
Statistical analysis description: Vitamin D ratio of Week 48 result over Baseline	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio of ratios
Point estimate	0.852
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.794
upper limit	0.914

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:	
Type 1 Collagen C-Telopeptide ratio of Week 48 result over Baseline	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio of ratios
Point estimate	0.655
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.609
upper limit	0.706

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
PTP ratio of Week 48 result over Baseline	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio of ratios
Point estimate	0.693
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.647
upper limit	0.741

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
Osteocalcin ratio of Week 48 result over Baseline	
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase

Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio of ratios
Point estimate	0.629
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.581
upper limit	0.68

Secondary: Change from Baseline at Week 48 in SF-12 Total Score, MCS and PCS

End point title	Change from Baseline at Week 48 in SF-12 Total Score, MCS and PCS

End point description:

SF-12 is a self-reported outcome measure assessing psychological wellness and the impact of health on an individual's everyday life. SF-12 questions make up 8 scales:Physical Functioning, Role Physical,Bodily Pain, General Health,Vitality, Social Functioning,Role Emotional, Mental Health.SF-12 total score ranges from 20 to 60 and higher score indicate a higher level of functioning. It was calculated by a clinician scoring 12-question survey filled by participants.Transformed physical component summary score (PCS) and transformed mental component summary score (MCS) are derived using sum of all 12 items and scored onto a 0-100 scale such that a higher score indicates a better health state and functioning. Baseline value wasdefined as latest pre-dose assessment (Day 1) value. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[70]	247[71]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Total Score, Week 48, n=205, 192	0.0 (± 5.15)	0.1 (± 5.66)		
MCS, Week 48, n=205, 192	2.397 (± 10.5232)	2.329 (± 9.9782)		
PCS, Week 48, n=205, 192	1.905 (± 8.6309)	1.444 (± 8.3938)		

Notes:

[70] - ITT-E Population

[71] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: HIVTSQs Total Score at indicated timepoints

End point title	HIVTSQs Total Score at indicated timepoints

End point description:

The HIV treatment satisfaction questionnaire (HIVTSQ) is a 10-item self-reported scale that measures overall satisfaction with treatment and by specific domains e.g. convenience, flexibility. The HIVTSQ items are summed up to produce a treatment satisfaction total score (0 to 60) and an individual satisfaction rating for each item (0 to 6) and two subscales: general satisfaction/clinical and lifestyle/ease subscales. The higher the score, the greater the improvement in treatment satisfaction as compared to the past few weeks. A smaller score represents a decline in treatment satisfaction compared to the past few weeks. Statistical analysis was performed based on Wilcoxon rank sum test. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Weeks 4, 12, 24 and 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[72]	247[73]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Week 4, n=243, 239	54.0 (± 6.37)	51.9 (± 8.53)		
Week 12, n=236, 226	56.1 (± 5.38)	53.6 (± 7.67)		
Week 24, n=225, 211	56.8 (± 4.55)	54.3 (± 7.27)		
Week 48, n=206, 191	57.0 (± 4.38)	55.4 (± 6.00)		

Notes:

[72] - ITT-E Population

[73] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.016 [74]
Method	Wilcoxon (Mann-Whitney)

Notes:

[74] - Week 4

Statistical analysis title	Statistical Analysis 4
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [75]
Method	Wilcoxon (Mann-Whitney)

Notes:

[75] - Week 48

Statistical analysis title	Statistical Analysis 3
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [76]
Method	Wilcoxon (Mann-Whitney)

Notes:

[76] - Week 24

Statistical analysis title	Statistical Analysis 2
Comparison groups	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase v ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [77]
Method	Wilcoxon (Mann-Whitney)

Notes:

[77] - Week 12

Secondary: Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 by subgroups

End point title	Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 by subgroups

End point description:

Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 by subgroups (age, race, country, Baseline plasma HIV-1 RNA [BPHR], Baseline CD4+ cell count [BCCC], Baseline Centers for Disease Control and Prevention [CDC] category and HIV-1 subtype) were assessed using the Snapshot algorithm (Missing, Switch or Discontinuation = Failure). Analysis was performed using a stratified analysis with CMH weights, adjusting for Baseline plasma HIV-1 RNA (=<versus [vs]. >100,000 c/mL) and CD4+ cell count (=<350 cells/mm^3 or >350 cells/mm^3). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT population. Percentage values are rounded off. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles)

End point type	Secondary

End point timeframe:

Week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248[78]	247[79]		
Units: Percentage of participants				
Age, <50 Years, n=212, 212	80	71		
Age, >=50 Years, n=36, 35	92	74		
Race, White, n=115, 107	86	80		
Race, Non-White, n=133,140	78	64		
Race, African-American/African Heritage, n=102,108	74	67		
Non-African-American/African Heritage, n=146, 139	88	75		
BPHR, <1000, n=5, 10	60	80		
BPHR, 1000 to <10,000, n=66, 62	83	77		
BPHR, 10,000 to <50,000, n=83, 81	84	74		
BPHR, 50,000 to <=100,000, n=25, 28	80	64		
BPHR, >100,000, n=69, 66	80	64		
BCCC, <200, n=64, 49	81	69		
BCCC, >=200, n=184, 198	82	72		
BCCC, <50, n=9, 15	67	60		
BCCC, 50 to <200, n=55, 34	84	74		
BCCC, 200 to <350, n=66, 74	89	73		
BCCC, 350 to <500, n=56, 65	79	74		
BCCC, >=500, n=62, 59	77	68		
CDC category, A, n=210, 208	81	71		
CDC category, B, n=27, 30	81	77		
CDC category, C, n=11, 9	91	56		
HIV-1 subtype: B vs Non-B, B, n=95, 111	80	69		
HIV-1 subtype: B vs Non-B, non-B, n=140, 131	84	73		
Argentina, n=24, 20	92	80		
Canada, n=11, 9	91	89		
France, n=7, 8	100	75		
Italy, n=17, 11	88	64		
Mexico, n=6, 5	100	60		
Portugal, n=4, 5	75	60		
Puerto Rico, n=0, 2	99999	100		
Russia, n=28, 22	89	82		
South Africa, n=33, 33	67	76		
Spain, n=23, 31	70	77		
Thailand, n=19, 21	95	52		
United States, n=62, 69	74	67		
United Kingdom, n=14, 11	93	64		

Notes:

[78] - ITT-E Population

[79] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with post-Baseline HIV-1 disease progression-Randomized Phase

End point title	Number of participants with post-Baseline HIV-1 disease progression-Randomized Phase

End point description:

Number of participants with post-Baseline HIV-1disease progression were assessed during study period. The CDC Classification System for HIV Infection is the medical classification system used by the United States Centers for Disease Control and Prevention (CDC) to classify HIV disease and infection. The clinical categories of HIV infection are defined as follows: Category A: Mildly symptomatic, Category B: Moderately symptomatic, Category C: Severely symptomatic. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Only those participants available at the specified time points were analyzed. Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT population. Only those participants who experienced a disease progression to CDC Class C or death were analyzed.

End point type	Secondary

End point timeframe:

Up to week 48

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[80]	7[81]		
Units: Participants				
CDC Class A to CDC Class C	5	4		
CDC Class B to CDC Class C	1	2		
CDC Class C to new CDC Class C	0	0		
CDC Class A, B or C to Death	1	1		

Notes:

[80] - ITT-E Population

[81] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with post-Baseline HIV-1 disease progression for DTG 50 mg/ABC 600 mg/3TC 300 mg QD (Randomized + Continuation Phase)

End point title	Number of participants with post-Baseline HIV-1 disease

	progression for DTG 50 mg/ABC 600 mg/3TC 300 mg QD (Randomized + Continuation Phase)

End point description:

Number of participants with post-Baseline HIV-1disease progression were assessed during study period. The CDC Classification System for HIV Infection is the medical classification system used by the United States Centers for Disease Control and Prevention (CDC) to classify HIV disease and infection. The clinical categories of HIV infection are defined as follows: Category A: Mildly symptomatic, Category B: Moderately symptomatic, Category C: Severely symptomatic. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. Only those participants available at the specified time points were analyzed. Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT population. Only those participants who experienced a disease progression to CDC Class C or death were analyzed

End point type	Secondary

End point timeframe:

Up to week 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD			
Subject group type	Subject analysis set			
Number of subjects analysed	9[82]			
Units: Participants				
CDC Class A to CDC Class C	6			
CDC Class B to CDC Class C	1			
CDC Class C to new CDC Class C	0			
CDC Class A, B or C to Death	2			

Notes:

[82] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with treatment emergent resistances for DTG 50 mg/ABC 600 mg/3TC 300 mg QD (Randomized + Continuation Phase)

End point title	Number of Participants with treatment emergent resistances for DTG 50 mg/ABC 600 mg/3TC 300 mg QD (Randomized + Continuation Phase)

End point description:

Number of participants, who meet confirmed virologic withdrawal criteria, with treatment emergent genotypic resistance to integrase strand transfer inhibitor (INSTI), Non-nucleoside reverse transcriptase inhibitor (NNRTI), nucleoside reverse transcriptase inhibitor (NRTI), protease inhibitors (PI) will be summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. On-treatment Genotypic Resistance Population comprised of all participants in the ITTE population with available On-treatment genotypic resistance data at the time confirmed virologic withdrawal criterion was met. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Up to week 432

End point values	DTG 50 mg/ABC 600 mg/3TC 300 mg QD			
Subject group type	Subject analysis set			
Number of subjects analysed	8[83]			
Units: Participants				
INSTI; n= 6	0			
NNRTI; n=8	1			
NRTI; n=8	1			
PI; n=8	0			

Notes:

[83] - On-treatment Genotypic Resistance Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with treatment emergent resistances for ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200mg QD (Randomized Phase)

End point title	Number of Participants with treatment emergent resistances for ATV 300 mg+RTV 100 mg+TDF 300 mg/FTC 200mg QD (Randomized Phase)[84]

End point description:

Number of participants, who meet confirmed virologic withdrawal criteria, with treatment emergent genotypic resistance to integrase strand transfer inhibitor (INSTI), Non-nucleoside reverse transcriptase inhibitor (NNRTI), nucleoside reverse transcriptase inhibitor (NRTI), protease inhibitors (PI) will be summarized. The Baseline value was defined as the latest pre-dose assessment (Day 1) value. On-treatment Genotypic Resistance Population comprised of all participants in the ITTE population with available On-treatment genotypic resistance data at the time confirmed virologic withdrawal criterion was met. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Up to week 48

Notes:

[84] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

End point values	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Participants				
INSTI; n= 3	1			
NNRTI; n=4	0			
NRTI; n=4	1			
PI; n=4	0			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality, Serious adverse events (SAEs) and non-SAEs were collected up to Week 48 for Randomized Phase; from Weeks 48 to 432 for Continuation Phase.

Adverse event reporting additional description:

All-Cause Mortality, SAEs and non-SAEs reported for Safety Population for Randomized Phase comprised all randomized participants who received atleast one dose of study treatment. Safety-ContinuationPopulation for ContinuationPhase comprised of all participants in DTG/ABC/3TCgroup who received at least 1 dose of study treatment in ContinuationPhase.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase

Reporting group description:

Participants received fixed dose combination (FDC) of DTG 50 milligram (mg)/ABC 600 mg/3TC 300 mg tablet once daily orally for 48 weeks in the Randomization Phase.

Reporting group title	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase

Reporting group description:

Participants received DTG 50 mg/ABC 600 mg/3TC 300 mg QD in the Continuation Phase until it was either locally approved or commercial supplies were available.

Reporting group title	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase

Reporting group description:

Participants received ATV 300 mg capsule, RTV 100 mg tablet, TDF 300 mg/ FTC 200 mg FDC tablet once daily orally for 48 weeks during Randomized Phase.

Serious adverse events	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 248 (4.84%)	13 / 149 (8.72%)	20 / 247 (8.10%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events			
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Iliac artery stenosis			

subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 248 (0.00%)	2 / 149 (1.34%)	2 / 247 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Reproductive system and breast disorders			
Endometriosis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
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			
Asthma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Panic attack			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute psychosis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Thermal burn			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Toxicity to various agents			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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			
Acute myocardial infarction			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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 coronary syndrome			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Cerebrovascular accident			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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			
Nausea			

subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis acute			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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
Cholecystitis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			

subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Diabetic foot			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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			
Acute kidney injury			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Scleroderma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis infective			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	2 / 247 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Lower respiratory tract infection			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Malaria			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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
Meningitis viral			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			

subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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
Acute hepatitis C			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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
Peritonitis			
subjects affected / exposed	0 / 248 (0.00%)	2 / 149 (1.34%)	0 / 247 (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
Diabetic foot infection			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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
Sepsis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 149 (0.67%)	0 / 247 (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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	1 / 248 (0.40%)	0 / 149 (0.00%)	0 / 247 (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

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

Non-serious adverse events	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Randomized Phase	DTG 50 mg/ABC 600 mg/3TC 300 mg QD-Continuation Phase	ATV 300mg+RTV 100 mg+TDF 300 mg/FTC 200 mg QD-Randomized Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	132 / 248 (53.23%)	30 / 149 (20.13%)	160 / 247 (64.78%)
Nervous system disorders			
Headache			
subjects affected / exposed	29 / 248 (11.69%)	12 / 149 (8.05%)	32 / 247 (12.96%)
occurrences (all)	49	18	38
Dizziness			
subjects affected / exposed	13 / 248 (5.24%)	0 / 149 (0.00%)	15 / 247 (6.07%)
occurrences (all)	16	0	15
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 248 (3.23%)	0 / 149 (0.00%)	15 / 247 (6.07%)
occurrences (all)	10	0	16
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	9 / 248 (3.63%)	0 / 149 (0.00%)	25 / 247 (10.12%)
occurrences (all)	17	0	29
Nausea			
subjects affected / exposed	46 / 248 (18.55%)	0 / 149 (0.00%)	49 / 247 (19.84%)
occurrences (all)	53	0	63
Diarrhoea			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	23 / 248 (9.27%)	8 / 149 (5.37%)	32 / 247 (12.96%)
occurrences (all)	24	8	37
Abdominal pain			
subjects affected / exposed	7 / 248 (2.82%)	0 / 149 (0.00%)	17 / 247 (6.88%)
occurrences (all)	7	0	20
Vomiting			
subjects affected / exposed	15 / 248 (6.05%)	0 / 149 (0.00%)	18 / 247 (7.29%)
occurrences (all)	16	0	42
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	10 / 248 (4.03%)	0 / 149 (0.00%)	26 / 247 (10.53%)
occurrences (all)	11	0	27

Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	14 / 247 (5.67%)
occurrences (all)	0	0	14
Hyperbilirubinaemia			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	13 / 247 (5.26%)
occurrences (all)	0	0	16
Ocular icterus			
subjects affected / exposed	0 / 248 (0.00%)	0 / 149 (0.00%)	18 / 247 (7.29%)
occurrences (all)	0	0	21
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	13 / 248 (5.24%)	0 / 149 (0.00%)	21 / 247 (8.50%)
occurrences (all)	14	0	23
Pruritus			
subjects affected / exposed	13 / 248 (5.24%)	0 / 149 (0.00%)	8 / 247 (3.24%)
occurrences (all)	17	0	8
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	12 / 248 (4.84%)	0 / 149 (0.00%)	18 / 247 (7.29%)
occurrences (all)	12	0	19
Arthralgia			
subjects affected / exposed	14 / 248 (5.65%)	0 / 149 (0.00%)	12 / 247 (4.86%)
occurrences (all)	19	0	15
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	13 / 248 (5.24%)	9 / 149 (6.04%)	17 / 247 (6.88%)
occurrences (all)	14	11	17
Nasopharyngitis			
subjects affected / exposed	15 / 248 (6.05%)	0 / 149 (0.00%)	14 / 247 (5.67%)
occurrences (all)	18	0	16
Upper respiratory tract infection			
subjects affected / exposed	18 / 248 (7.26%)	13 / 149 (8.72%)	21 / 247 (8.50%)
occurrences (all)	21	19	24

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 August 2013	Amendment No. 01: This amendment includes the removal of the Child-Pugh Classification due to its unsuitability for use in participants with no known hepatic impairment. Other minor clarifications and corrections have been incorporated, including an update to Figure 2, Virologic Criteria for Subject Management at Week 24, to differentiate between the two scenarios for re-testing HIV-1 RNA levels.
11 August 2014	Amendment No. 2: Changes made to the UK country specific information on study duration (Appendix 5) to comply with requests from the UK MHRA. The medical monitor contact information has also been updated.
19 June 2018	Amendment No. 3: Changes were made to the protocol to manage and mitigate risks following identification of a potential safety issue related to neural tube defect in infants born to women with exposure to dolutegravir at the time of conception. i. The Risk Assessment table (Section 1.3.1.) was updated to include language regarding risk and mitigation of neural tube defects. ii. Inclusion criterion #2 (Section 4.2.) was updated to exclude the double barrier method of contraception, and refer to the Modified List of Highly Effective Methods for Avoiding Pregnancy in Females of Reproductive Potential. iii. The withdrawal criteria (Section 4.5.) were updated to include a reminder that females of reproductive potential who change their minds and desire to be pregnant, or who state they no longer are willing to comply with the approved pregnancy avoidance methods, should also be withdrawn from the study. iv. The Time and Events table (Section 6.1.) was updated to include a reminder for investigators to check at every visit that females of reproductive potential are avoiding pregnancy. v. Appendix 6 was added: Modified List of Highly Effective Methods for Avoiding Pregnancy in Females of Reproductive Potential. vi. Administrative updates were made.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported