Clinical trial results:
A Phase III, Randomized, Multicenter, Parallel-group, Open- Label Study Evaluating the Efficacy, Safety, and Tolerability of Long-Acting Intramuscular Cabotegravir and Rilpivirine for Maintenance of Virologic Suppression Following Switch from an Integrase Inhibitor Single Tablet Regimen in HIV-1 Infected Antiretroviral Therapy Naive Adult Participants

Summary

EudraCT number	2016-001646-25
Trial protocol	ES GB DE NL IT
Global end of trial date	

Results information

Result version number	v2 (current)
This version publication date	25 October 2019
First version publication date	24 August 2019
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	201584

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ViiV Healthcare
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
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	Interim
Date of interim/final analysis	27 November 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 August 2018
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferior antiviral activity of switching to intramuscular CAB LA + RPV LA every 4 weeks compared to continuation of ABC/DTG/3TC over 48 weeks in HIV-1 antiretroviral naïve participants.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 October 2016
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Scientific research
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 23
Country: Number of subjects enrolled	France: 43
Country: Number of subjects enrolled	Germany: 44
Country: Number of subjects enrolled	Italy: 38
Country: Number of subjects enrolled	Japan: 20
Country: Number of subjects enrolled	Netherlands: 5
Country: Number of subjects enrolled	Russian Federation: 93
Country: Number of subjects enrolled	South Africa: 32
Country: Number of subjects enrolled	Spain: 157
Country: Number of subjects enrolled	United Kingdom: 25
Country: Number of subjects enrolled	United States: 86
Worldwide total number of subjects	566
EEA total number of subjects	312

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)	563
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This non-inferiority study evaluated antiviral activity of switching to intramuscular long acting carbotegravir (CAB) and rilpivirine (RPV) every 4 weeks compared to continuation of abacavir (ABC)/dolutegravir (DTG)/lamivudine (3TC) over 48 weeks in virologically suppressed participants with human immunodeficiency type 1 infection

Pre-assignment

Screening details:

A total of 631 participants were enrolled into the Induction Phase of the study. 566 participants were subsequently randomized. Two randomized participants did not receive study treatment. This study was conducted in 11 countries. The results presented are based on Week 48 primary analysis

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	CAB LA + RPV LA (Q4W)

Arm description:

Participants who received ABC/DTG/3TC for 20 Weeks (Week [-20] to Day 1) in the Induction Phase and who have an HIV-1 ribonucleic acid (RNA) <50 copies per millilter (c/mL) at Week (-4) entered Maintenance Phase (Day 1 to Week 100) to begin oral therapy with CAB 30 milligram (mg) + RPV 25 mg once daily for 4 Weeks. At Week 4b visit, participants received last dose of oral CAB + RPV and first dose CAB LA 600 mg + RPV LA 900 mg injections. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg at Week 8 and every four weeks (Q4W) through Week 100. After completion of Maintenance Phase, participants who chose to enter Extension Phase will continue to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up (LTFU) period.

Arm type	Experimental
Investigational medicinal product name	Cabotegravir oral
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received cabotegravir (CAB) 30 milligram (mg) tablet once daily from Day 1 to Week 4b approximately the same time each day with a meal

Investigational medicinal product name	Cabotegravir Injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received CAB 3 milliliter (mL; 600 mg) IM injection at Week 4b after the last dose of CAB oral regimen. Participants then received CAB 2 mL (400 mg) injections every 4 weeks from Week 8 to Week 100

Investigational medicinal product name	Rilpivirine Injection
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection

Routes of administration	Intramuscular use

Dosage and administration details:

Participants received RPV 3 mL (900 mg) IM injection at Week 4b after the last dose of RPV oral regimen. Participants then received RPV 2 mL (600 mg) injections every 4 weeks from Week 8 to Week 100

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

Dosage and administration details:

Participants received rilpivirine (RPV) 25 mg tablet once daily from Day 1 to Week 4b approximately the same time each day with a meal

Arm title	ABC/ DTG/ 3TC

Arm description:

During Maintenance Phase (Day 1 to Week 100), participants continued to receive ABC/DTG/3TC. After completion of Maintenance Phase, participants who chose to enter the Extension Phase have the option to complete the study or switch to CAB LA+RPV LA

Arm type	Active comparator
Investigational medicinal product name	ABC/DTG/3TC Single Tablet Regimen (STR)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received abacavir (ABC) 600 mg/ dolutegravir (DTG) 50 mg/ lamivudine (3TC) 300 mg film coated tablet once daily as single tablet regimen from Day 1 to Week 100

Number of subjects in period 1	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC
Started	283	283
Completed	0	0
Not completed	283	283
Physician decision	2	5
Consent withdrawn by subject	7	7
Adverse event, non-fatal	9	4
On-going at the time of analysis	258	261
Lost to follow-up	2	2
Lack of efficacy	5	3
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	CAB LA + RPV LA (Q4W)
Reporting group description:	
Participants who received ABC/DTG/3TC for 20 Weeks (Week [-20] to Day 1) in the Induction Phase and who have an HIV-1 ribonucleic acid (RNA) <50 copies per millilter (c/mL) at Week (-4) entered Maintenance Phase (Day 1 to Week 100) to begin oral therapy with CAB 30 milligram (mg) + RPV 25 mg once daily for 4 Weeks. At Week 4b visit, participants received last dose of oral CAB + RPV and first dose CAB LA 600 mg + RPV LA 900 mg injections. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg at Week 8 and every four weeks (Q4W) through Week 100. After completion of Maintenance Phase, participants who chose to enter Extension Phase will continue to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up (LTFU) period.	
Reporting group title	ABC/ DTG/ 3TC
Reporting group description:	
During Maintenance Phase (Day 1 to Week 100), participants continued to receive ABC/DTG/3TC. After completion of Maintenance Phase, participants who chose to enter the Extension Phase have the option to complete the study or switch to CAB LA+RPV LA	

Reporting group values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC	Total
Number of subjects	283	283	566
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	281	282	563
From 65-84 years	2	1	3
85 years and over	0	0	0
Age Continuous			
Intent-to-Treat Exposed			
Units: Years			
arithmetic mean	35.9	36.0	
standard deviation	± 10.17	± 9.82	-
Sex: Female, Male			
Intent-to-Treat Exposed			
Units: Subjects			
Female	63	64	127
Male	220	219	439
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	3	6	9
Asian-Central/South Asian Heritage	2	1	3
Asian-East Asian Heritage	1	2	3
Asian-South East Asian Heritage	1	0	1
Asian-Japanese Heritage	8	12	20

Black or African American	47	56	103
Native Hawaiian or other Pacific Islander	1	0	1
White-Arabic/North African Heritage	5	3	8
White-White /Caucasian/European Heritage	211	198	409
Multiple	4	3	7
Missing	0	2	2

End points

End points reporting groups

Reporting group title	CAB LA + RPV LA (Q4W)

Reporting group description:

Participants who received ABC/DTG/3TC for 20 Weeks (Week [-20] to Day 1) in the Induction Phase and who have an HIV-1 ribonucleic acid (RNA) <50 copies per millilter (c/mL) at Week (-4) entered Maintenance Phase (Day 1 to Week 100) to begin oral therapy with CAB 30 milligram (mg) + RPV 25 mg once daily for 4 Weeks. At Week 4b visit, participants received last dose of oral CAB + RPV and first dose CAB LA 600 mg + RPV LA 900 mg injections. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg at Week 8 and every four weeks (Q4W) through Week 100. After completion of Maintenance Phase, participants who chose to enter Extension Phase will continue to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up (LTFU) period.

Reporting group title	ABC/ DTG/ 3TC

Reporting group description:

During Maintenance Phase (Day 1 to Week 100), participants continued to receive ABC/DTG/3TC. After completion of Maintenance Phase, participants who chose to enter the Extension Phase have the option to complete the study or switch to CAB LA+RPV LA

Subject analysis set title	CAB LA
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received CAB 30 mg once daily for 4 Weeks during Maintenance Phase (Day 1 to Week 100). At Week 4b visit, participants received last dose of oral CAB and first dose CAB LA 600 mg injections. Participants received IM injections of CAB LA 400 mg at Week 8 and every four weeks through Week 100.

Subject analysis set title	RPV LA
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received RPV 25 mg once daily for 4 Weeks during Maintenance Phase (Day 1 to Week 100). At Week 4b visit, participants received last dose of oral RPV and first dose CAB LA 900 mg injections. Participants received IM injections of RPV LA 600 mg at Week 8 and every four weeks through Week 100.

Primary: Percentage of participants with virologic failure (HIV-1 ribonucleic acid [RNA] >=50 copies per millilter [mL]) using snapshot algorithm at Week 48

End point title	Percentage of participants with virologic failure (HIV-1 ribonucleic acid [RNA] >=50 copies per millilter [mL]) using snapshot algorithm at Week 48

End point description:

Percentage of participants with virologic failure endpoint (HIV-1 RNA>=50 c/mL) as per Food and Drug Administration (FDA) snapshot algorithm at Week 48 was assessed to demonstrate the noninferior antiviral activity of switching to intramuscular (IM) CAB LA+RPV LA every 4 weeks compared to continuation of ABC/DTG/3TC regimen over 48 weeks in HIV-1 infected ARTexperienced participants. The HIV-1 RNA >=50 copies/mL per snapshot algorithm was determined by the last on-treatment HIV-1 RNA measurement within the Week 48 analysis visit window (+/- 6 weeks) or at time of discontinuation (if discontinuation occurred prior to Week 48 for reasons other than Adverse Event). Intent-to treat exposed (ITT-E) participants included all randomized participants who received at least one dose of Investigational Product (IP) during the Maintenance Phase. Participants were analyzed according to the randomized treatment regardless of what treatment actually received.

End point type	Primary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[1]	283[2]		
Units: Percentage of Participants				
number (not applicable)	2.1	2.5		

Notes:

[1] - ITT-E Population

[2] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Non-inferiority in the proportion of participants with virologic failure at Week 48 (per FDA's snapshot algorithm for
assessing HIV-1 RNA >=50 c/mL) can be concluded if the upper bound of a two-sided 95% confidence interval (CI) for the difference in failure rates between the two treatment arms (CAB – ABC/DTG/3TC) is less than 6%.

Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Adjusted difference in proportion
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.8
upper limit	2.1

Notes:

[3] - Adjusted difference in proportion was based on Cochran-Mantel Haenszel stratified analysis adjusting for the following baseline stratification factors: sex at birth (Male, Female) and Induction Baseline (Week -20) HIV-1 RNA (<100,000 >=100,000 c/mL)

Secondary: Percentage of participants with HIV-1 RNA <50 copies/mL using snapshot algorithm at Week 48

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

End point description:

Percentage of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 using FDA snapshot algorithm was assessed to demonstrate antiviral and immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to continuation of ABC/DTG/3TC. The HIV-1 RNA <50 copies/mL per snapshot algorithm was determined by last on-treatment HIV-1 RNA measurement within the Week 48 analysis visit window (+/- 6 weeks). Participants with no data in the analysis window were classificated as non-responders.

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[4]	283[5]		
Units: Percentage of Participants	94	93		

Notes:

[4] - ITT-E Population

[5] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Non-inferiority in the proportion of participants with HIV-1 RNA<50 c/mL at Week 48 (per FDA's snapshot algorithm) can be concluded if the lower bound of a two-sided 95% confidence interval for the difference in success rates between the two treatment arms (CAB – ABC/DTG/3TC) is more than -10%

Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Adjusted difference in proportion
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	4.5

Notes:

[6] - Adjusted difference in proportion was based on Cochran-Mantel Haenszel stratified analysis adjusting for the following baseline stratification factors: sex at birth (Male, Female) and Induction Baseline (Week -20) HIV-1 RNA (<100,000 >=100,000 c/mL)

Secondary: Number of participants with HIV-1 RNA <200 copies/mL using snapshot algorithm at Week 48

End point title	Number of participants with HIV-1 RNA <200 copies/mL using snapshot algorithm at Week 48

End point description:

Percentage of participants with plasma HIV-1 RNA <200 copies/mL at Week 48 using the snapshot algorithm was assessed based on the antiviral and immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to continuation of ABC/DTG/3TC

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[7]	283[8]		
Units: Percentage of Participants				
number (confidence interval 95%)	94 (91 to 97)	94 (91 to 97)		

Notes:

[7] - ITT-E Population

[8] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with confirmed virologic failure (CVF) during the Maintenance Phase

End point title	Number of participants with confirmed virologic failure (CVF) during the Maintenance Phase

End point description:

The CVF is defined as rebound as indicated by two consecutive plasma HIV-1-RNA levels >=200 copies/mL after prior suppression to <200 copies/mL.

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[9]	283[10]		
Units: Participants	4	3		

Notes:

[9] - ITT-E Population

[10] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for plasma HIV-1 RNA at Week 48

End point title	Absolute values for plasma HIV-1 RNA at Week 48

End point description:

Plasma for quantitative HIV-1 RNA were collected at indicated time points. Logarithm to base 10 (log10) values for plasma HIV-1 RNA has been presented. Only those participants with data available at the specified data points were analyzed

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[11]	283[12]		
Units: log10 copies/mL				
arithmetic mean (standard deviation)	1.513 (± 0.0954)	1.518 (± 0.1152)		

Notes:

[11] - ITT-E Population

[12] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for plasma HIV-1 RNA at Week 48

End point title	Change from Baseline values for plasma HIV-1 RNA at Week 48

End point description:

Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline was defined as: HIV-1 RNA(log 10) at Week 48 minus HIV-1 RNA(log 10) at Baseline. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[13]	283[14]		
Units: log10 copies/mL				
arithmetic mean (standard deviation)	-0.006 (± 0.1026)	0.001 (± 0.1435)		

Notes:

[13] - ITT-E Population

[14] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for CD4+ lymphocyte count at Week 48

End point title	Absolute values for CD4+ lymphocyte count at Week 48

End point description:

Blood samples were collected and CD4+ cell count assessment by flow cyclometry was carried out to evaluate the immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to ABC/DTG/3TC. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[15]	283[16]		
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)	703.2 (± 285.75)	731.2 (± 272.49)		

Notes:

[15] - ITT-E Population

[16] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for CD4+ lymphocyte count at Week 48

End point title	Change from Baseline values for CD4+ lymphocyte count at Week 48

End point description:

Blood samples were collected and CD4+ cell count assessment by flow cyclometry was carried out to evaluate the immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to ABC/DTG/3TC. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline was defined as post-dose visit value at Week 48 minus Maintenance Baseline value. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[17]	283[18]		
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)	40.2 (± 195.17)	79.9 (± 194.55)		

Notes:

[17] - ITT-E Population

[18] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with disease progression

End point title	Number of participants with disease progression

End point description:

Data for participants who experienced disease progression to Centers for Disease Control and Prevention (CDC) Stage III or death has been presented. CDC stage is derived according to lowest post baseline

CD4+ T-lympohocyte count and/or occurrence of AIDS-defining conditons (per 2014 CDC criteria).

End point type	Secondary

End point timeframe:

Day 1 up to an average of 59 weeks

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[19]	283[20]		
Units: Participants	9	11		

Notes:

[19] - ITT-E Population

[20] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with non-serious adverse events (non-SAEs) and serious adverse events (SAEs)

End point title	Number of participants with non-serious adverse events (non-SAEs) and serious adverse events (SAEs)

End point description:

An AE is any untoward medical occurrence temporally associated with use of a study treatment, whether or not considered related to study treatment. A SAE is any untoward medical occurrence that, at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity, is a congenital anomaly/birth defect, associated with liver injury and impaired liver function or any other situations as per medical or scientific judgment. Safety Population: all randomized participants who received at least 1 dose of IP during maintenance phase and assessed according to actual treatment received. All Maintenance Phase AEs was presented including AEs with start date occurring on/after date of 1st dose of randomized treatment, up to and including start date of LTFU antiretroviral therapy for participants who discontinued from Q4W arm. Non-SAE counts in >=5% of participants within any arm is reported

End point type	Secondary

End point timeframe:

Day 1 up to an average of 59 Weeks

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[21]	283[22]		
Units: Participants				
Any non-SAE	252	138		
Any SAE	18	12		

Notes:

[21] - Safety Population

[22] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with severity of adverse events

End point title	Number of participants with severity of adverse events

End point description:

Severity of adverse events (AEs) were defined as per The Division of acquired immuno deficiency syndrome (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table) Version 2.0, November 2014. Severity grades for AEs were as Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (Potentially life-threatening) and Grade 5 were all deaths related to an AE. All Maintenance Phase adverse events have been presented, which includes AEs with start date occuring on or after the date of first dose of randomized study treatment, up to and including the start date of LTFU antiretroviral therapy for participants who discontinued from the Q4W arm.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[23]	283[24]		
Units: Participants				
Grade 1	93	119		
Grade 2	143	95		
Grade 3	23	10		
Grade 4	8	1		
Grade 5	0	0		

Notes:

[23] - Safety Population

[24] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters over time including Week 48: basophils, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets

End point title	Absolute values for hematology parameters over time including Week 48: basophils, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets

End point description:

Blood samples were collected for the analysis of hematology parameters including basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets at indicated time points. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[25]	283[26]		
Units: 10^9 cells per Liter				
arithmetic mean (standard deviation)				
Basophils, Baseline (Day 1), n=283, 283	0.022 (± 0.0124)	0.022 (± 0.0138)		
Basophils, Week 4, n=277, 270	0.024 (± 0.0136)	0.024 (± 0.0142)		
Basophils, Week 8, n=210, 272	0.023 (± 0.0135)	0.023 (± 0.0122)		
Basophils, Week 12, n=267, 272	0.025 (± 0.0166)	0.023 (± 0.0144)		
Basophils, Week 16, n=247, 259	0.030 (± 0.0212)	0.028 (± 0.0209)		
Basophils, Week 20, n=247, 259	0.035 (± 0.0254)	0.032 (± 0.0256)		
Basophils, Week 24, n=256, 260	0.037 (± 0.0245)	0.036 (± 0.0256)		
Basophils, Week 28, n=239, 258	0.039 (± 0.0249)	0.038 (± 0.0247)		
Basophils, Week 32, n=246, 263	0.044 (± 0.0254)	0.038 (± 0.0246)		
Basophils, Week 36, n=250, 259	0.042 (± 0.0237)	0.040 (± 0.0250)		
Basophils, Week 40, n=244, 245	0.041 (± 0.0248)	0.041 (± 0.0252)		
Basophils, Week 44, n=249, 260	0.040 (± 0.0246)	0.040 (± 0.0257)		
Basophils, Week 48, n=239, 258	0.038 (± 0.0214)	0.038 (± 0.0246)		
Eosinophils, Baseline (Day 1), n=283, 283	0.142 (± 0.1238)	0.141 (± 0.1449)		
Eosinophils, Week 4, n=277, 270	0.164 (± 0.1470)	0.154 (± 0.1535)		
Eosinophils, Week 8, n=210, 272	0.169 (± 0.1401)	0.150 (± 0.1393)		
Eosinophils, Week 12, n=267, 272	0.165 (± 0.1375)	0.157 (± 0.1481)		
Eosinophils, Week 16, n=247, 259	0.177 (± 0.1538)	0.162 (± 0.1434)		
Eosinophils, Week 20, n=247, 259	0.185 (± 0.1617)	0.166 (± 0.1675)		
Eosinophils, Week 24, n=256, 260	0.193 (± 0.1591)	0.172 (± 0.1518)		
Eosinophils, Week 28, n=239, 258	0.206 (± 0.1634)	0.179 (± 0.1659)		
Eosinophils, Week 32, n=246, 263	0.206 (± 0.1779)	0.169 (± 0.1466)		
Eosinophils, Week 36, n=250, 259	0.209 (± 0.2043)	0.172 (± 0.1540)		
Eosinophils, Week 40, n=244, 245	0.203 (± 0.1837)	0.174 (± 0.1495)		
Eosinophils, Week 44, n=249, 260	0.198 (± 0.1867)	0.180 (± 0.1723)		
Eosinophils, Week 48, n=239, 258	0.182 (± 0.1508)	0.172 (± 0.1533)		
Leukocytes, Baseline (Day 1), n=283, 283	5.82 (± 1.792)	5.68 (± 1.684)		
Leukocytes, Week 4, n=279, 272	6.41 (± 1.989)	6.11 (± 1.770)		

Leukocytes, Week 8, n=211, 275	6.04 (± 1.806)	6.00 (± 1.714)		
Leukocytes, Week 12, n=270, 275	5.88 (± 1.590)	6.08 (± 1.836)		
Leukocytes, Week 16, n=252, 265	6.08 (± 2.045)	6.11 (± 1.887)		
Leukocytes, Week 20, n=254, 265	6.08 (± 1.788)	6.15 (± 1.926)		
Leukocytes, Week 24, n=258, 264	6.11 (± 1.841)	6.16 (± 2.046)		
Leukocytes, Week 28, n=244, 263	6.17 (± 1.929)	6.17 (± 1.939)		
Leukocytes, Week 32, n=253, 266	6.07 (± 1.925)	6.12 (± 1.918)		
Leukocytes, Week 36, n=252, 259	6.11 (± 1.992)	6.23 (± 2.104)		
Leukocytes, Week 40, n=246, 253	5.96 (± 1.773)	6.12 (± 2.076)		
Leukocytes, Week 44, n=256, 262	6.03 (± 2.000)	6.19 (± 1.970)		
Leukocytes, Week 48, n=243, 260	5.85 (± 1.884)	5.99 (± 1.986)		
Lymphocytes, Baseline (Day 1), n=283, 283	2.022 (± 0.6893)	1.957 (± 0.6408)		
Lymphocytes, Week 4, n=277, 270	2.227 (± 0.7321)	2.197 (± 0.7198)		
Lymphocytes, Week 8, n=210, 272	2.102 (± 0.6980)	2.110 (± 0.7015)		
Lymphocytes, Week 12, n=267, 272	2.032 (± 0.6095)	2.117 (± 0.7162)		
Lymphocytes, Week 16, n=247, 259	2.028 (± 0.6931)	2.130 (± 0.7245)		
Lymphocytes, Week 20, n=247, 259	2.028 (± 0.6284)	2.121 (± 0.6995)		
Lymphocytes, Week 24, n=256, 260	2.014 (± 0.6456)	2.111 (± 0.7092)		
Lymphocytes, Week 28, n=239, 258	2.051 (± 0.6592)	2.106 (± 0.6679)		
Lymphocytes, Week 32, n=246, 263	2.037 (± 0.6543)	2.112 (± 0.6950)		
Lymphocytes, Week 36, n=250, 259	2.023 (± 0.6878)	2.098 (± 0.6921)		
Lymphocytes, Week 40, n=244, 245	2.021 (± 0.6646)	2.030 (± 0.6357)		
Lymphocytes, Week 44, n=249, 260	1.997 (± 0.6748)	2.068 (± 0.6754)		
Lymphocytes, Week 48, n=239, 258	1.926 (± 0.6126)	2.003 (± 0.7651)		
Monocytes, Baseline (Day 1), n=283, 283	0.382 (± 0.1666)	0.366 (± 0.1705)		
Monocytes, Week 4, n=277, 270	0.422 (± 0.1778)	0.398 (± 0.1778)		
Monocytes, Week 8, n=210, 272	0.415 (± 0.1824)	0.380 (± 0.1771)		
Monocytes, Week 12, n=267, 272	0.395 (± 0.1662)	0.383 (± 0.1570)		
Monocytes, Week 16, n=247, 259	0.438 (± 0.1859)	0.409 (± 0.1810)		
Monocytes, Week 20, n=247, 259	0.455 (± 0.1927)	0.423 (± 0.1904)		
Monocytes, Week 24, n=256, 260	0.438 (± 0.1859)	0.438 (± 0.1897)		
Monocytes, Week 28, n=239, 258	0.471 (± 0.1916)	0.447 (± 0.2003)		
Monocytes, Week 32, n=246, 263	0.462 (± 0.1898)	0.459 (± 0.2107)		
Monocytes, Week 36, n=250, 259	0.458 (± 0.2116)	0.456 (± 0.2021)		
Monocytes, Week 40, n=244, 245	0.438 (± 0.1740)	0.442 (± 0.2038)		

Monocytes, Week 44, n=249, 260	0.440 (± 0.1907)	0.428 (± 0.1965)		
Monocytes, Week 48, n=239, 258	0.402 (± 0.1911)	0.396 (± 0.1857)		
Neutrophils, Baseline (Day 1), n=283, 283	3.246 (± 1.3715)	3.205 (± 1.2803)		
Neutrophils, Week 4, n=277, 270	3.573 (± 1.5681)	3.342 (± 1.3344)		
Neutrophils, Week 8, n=210, 272	3.334 (± 1.3166)	3.316 (± 1.3588)		
Neutrophils, Week 12, n=267, 272	3.271 (± 1.2151)	3.379 (± 1.4884)		
Neutrophils, Week 16, n=247, 259	3.410 (± 1.7208)	3.432 (± 1.5052)		
Neutrophils, Week 20, n=247, 259	3.406 (± 1.4209)	3.433 (± 1.5620)		
Neutrophils, Week 24, n=256, 260	3.428 (± 1.4938)	3.424 (± 1.6766)		
Neutrophils, Week 28, n=239, 258	3.439 (± 1.5379)	3.423 (± 1.5514)		
Neutrophils, Week 32, n=246, 263	3.367 (± 1.5670)	3.392 (± 1.4892)		
Neutrophils, Week 36, n=250, 259	3.388 (± 1.5215)	3.468 (± 1.6269)		
Neutrophils, Week 40, n=244, 245	3.274 (± 1.3654)	3.477 (± 1.7021)		
Neutrophils, Week 44, n=249, 260	3.398 (± 1.5679)	3.503 (± 1.5486)		
Neutrophils, Week 48, n=239, 258	3.309 (± 1.4923)	3.419 (± 1.5186)		
Platelets, Baseline (Day 1), n=283, 282	226.7 (± 55.39)	230.6 (± 58.33)		
Platelets, Week 4, n=278, 269	233.1 (± 56.85)	233.4 (± 56.56)		
Platelets, Week 8, n=207, 273	226.9 (± 53.23)	232.0 (± 56.31)		
Platelets, Week 12, n=269, 271	226.6 (± 55.07)	235.5 (± 57.26)		
Platelets, Week 16, n=251, 263	225.5 (± 55.49)	239.9 (± 70.40)		
Platelets, Week 20, n=255, 264	233.8 (± 60.98)	243.4 (± 62.06)		
Platelets, Week 24, n=256, 261	233.9 (± 58.12)	244.2 (± 59.95)		
Platelets, Week 28, n=245, 258	233.7 (± 61.56)	247.2 (± 63.18)		
Platelets, Week 32, n=249, 262	235.0 (± 62.74)	245.3 (± 60.25)		
Platelets, Week 36, n=248, 259	237.3 (± 58.56)	248.1 (± 59.57)		
Platelets, Week 40, n=244, 254	233.9 (± 56.93)	247.4 (± 63.85)		
Platelets, Week 44, n=254, 261	236.7 (± 58.18)	249.5 (± 71.56)		
Platelets, Week 48, n=240, 255	232.8 (± 57.07)	246.0 (± 70.35)		

Notes:

[25] - Safety Population

[26] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters over time including Week 48: erythrocyte mean corpuscular volume

End point title	Absolute values for hematology parameters over time including Week 48: erythrocyte mean corpuscular volume

End point description:

Blood samples were collected for the analysis of hematology parameter including erythrocyte mean corpuscular volume at indicated timepoints. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[27]	283[28]		
Units: Femtoliters				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=283, 283	94.8 (± 4.94)	94.3 (± 5.69)		
Week 4, n=279, 273	94.1 (± 4.77)	94.6 (± 5.85)		
Week 8, n=211, 275	92.3 (± 4.86)	94.6 (± 5.78)		
Week 12, n=270, 275	91.0 (± 4.64)	94.0 (± 5.81)		
Week 16, n=254, 265	89.9 (± 4.43)	94.1 (± 5.78)		
Week 20, n=255, 267	89.3 (± 4.46)	93.9 (± 5.64)		
Week 24, n=259, 264	89.4 (± 4.33)	93.8 (± 5.69)		
Week 28, n=246, 265	89.3 (± 4.64)	93.5 (± 5.78)		
Week 32, n=254, 267	89.6 (± 4.69)	93.6 (± 5.90)		
Week 36, n=252, 261	89.5 (± 4.65)	94.1 (± 5.65)		
Week 40, n=246, 255	90.3 (± 4.62)	94.4 (± 6.09)		
Week 44, n=256, 262	90.7 (± 5.05)	94.6 (± 6.32)		
Week 48, n=243, 260	91.2 (± 5.21)	95.4 (± 6.60)		

Notes:

[27] - Safety Population

[28] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters over time including Week 48: erythrocytes

End point title	Absolute values for hematology parameters over time including Week 48: erythrocytes

End point description:

Blood samples were collected for the analysis of hematology parameters including erythrocytes at indicated timepoints. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[29]	283[30]		
Units: 10^12 cells per Liter				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=283, 283	4.59 (± 0.434)	4.65 (± 0.412)		
Week 4, n=279, 273	4.67 (± 0.423)	4.62 (± 0.406)		
Week 8, n=211, 275	4.76 (± 0.435)	4.67 (± 0.410)		
Week 12, n=270, 275	4.82 (± 0.435)	4.66 (± 0.419)		
Week 16, n=254, 265	4.87 (± 0.430)	4.66 (± 0.407)		
Week 20, n=255, 267	4.89 (± 0.418)	4.64 (± 0.410)		
Week 24, n=259, 264	4.87 (± 0.418)	4.67 (± 0.425)		
Week 28, n=246, 265	4.87 (± 0.416)	4.69 (± 0.395)		
Week 32, n=254, 267	4.83 (± 0.435)	4.66 (± 0.418)		
Week 36, n=252, 261	4.82 (± 0.403)	4.64 (± 0.395)		
Week 40, n=246, 255	4.81 (± 0.407)	4.63 (± 0.409)		
Week 44, n=256, 262	4.79 (± 0.425)	4.59 (± 0.403)		
Week 48, n=243, 260	4.74 (± 0.443)	4.59 (± 0.437)		

Notes:

[29] - Safety Population

[30] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters over time including Week 48: hemoglobin

End point title	Absolute values for hematology parameters over time including Week 48: hemoglobin

End point description:

Blood samples were collected for the analysis of hematology parameter including hemoglobin at indicated timepoints. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[31]	283[32]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=283, 283	142.5 (± 13.59)	143.1 (± 13.51)		
Week 4, n=279, 273	144.3 (± 13.34)	143.4 (± 13.47)		
Week 8, n=211, 275	143.9 (± 13.84)	144.7 (± 13.59)		
Week 12, n=270, 275	144.5 (± 13.89)	144.7 (± 14.66)		
Week 16, n=254, 265	145.3 (± 13.52)	144.6 (± 13.88)		
Week 20, n=255, 267	145.4 (± 12.69)	144.8 (± 13.87)		
Week 24, n=259, 264	145.0 (± 13.14)	145.3 (± 14.07)		
Week 28, n=246, 265	145.3 (± 12.80)	146.5 (± 14.17)		
Week 32, n=254, 267	145.1 (± 13.37)	146.2 (± 14.80)		
Week 36, n=252, 261	144.6 (± 12.27)	146.2 (± 13.85)		
Week 40, n=246, 255	145.9 (± 12.32)	146.2 (± 13.85)		
Week 44, n=256, 262	145.1 (± 12.79)	145.0 (± 14.13)		
Week 48, n=243, 260	143.8 (± 13.56)	145.4 (± 14.56)		

Notes:

[31] - Safety Population

[32] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters over time including Week 48: hematocrit

End point title	Absolute values for hematology parameters over time including Week 48: hematocrit

End point description:

Blood samples were collected for the analysis of hematology parameters including hematocrit at indicated timepoints. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[33]	283[34]		
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=283, 283	0.4341 (± 0.03889)	0.4370 (± 0.03887)		
Week 4, n=279, 273	0.4387 (± 0.03809)	0.4363 (± 0.03832)		
Week 8, n=211, 275	0.4382 (± 0.04056)	0.4403 (± 0.03978)		
Week 12, n=270, 275	0.4377 (± 0.04020)	0.4373 (± 0.04144)		
Week 16, n=254, 265	0.4366 (± 0.03769)	0.4371 (± 0.03890)		
Week 20, n=255, 267	0.4363 (± 0.03574)	0.4349 (± 0.03839)		
Week 24, n=259, 264	0.4351 (± 0.03580)	0.4366 (± 0.03901)		
Week 28, n=246, 265	0.4342 (± 0.03519)	0.4374 (± 0.03867)		
Week 32, n=254, 267	0.4318 (± 0.03623)	0.4347 (± 0.04025)		
Week 36, n=252, 261	0.4301 (± 0.03392)	0.4349 (± 0.03774)		
Week 40, n=246, 255	0.4328 (± 0.03433)	0.4358 (± 0.03845)		
Week 44, n=256, 262	0.4332 (± 0.03570)	0.4328 (± 0.03847)		
Week 48, n=243, 260	0.4310 (± 0.03875)	0.4361 (± 0.04156)		

Notes:

[33] - Safety Population

[34] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters over time including Week 48: Alanine aminotransferase (ALT), alkaline phosphatase (ALP), aspartate aminotransferase (AST) and creatinine kinase (CK)

End point title	Absolute values for clinical chemistry parameters over time including Week 48: Alanine aminotransferase (ALT), alkaline phosphatase (ALP), aspartate aminotransferase (AST) and creatinine kinase (CK)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including ALT, ALP, AST and CK at indicated timepoints. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[35]	283[36]		
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT, Baseline (Day 1), n=283, 283	28.7 (± 125.27)	19.5 (± 14.76)		
ALT, Week 4, n=281, 277	25.1 (± 64.74)	17.9 (± 11.10)		
ALT, Week 8, n=212, 278	20.8 (± 17.43)	18.4 (± 11.34)		
ALT, Week 12, n=270, 276	21.4 (± 16.94)	19.2 (± 11.29)		
ALT, Week 16, n=255, 269	21.6 (± 17.61)	20.3 (± 13.34)		
ALT, Week 20, n=260, 272	25.8 (± 72.51)	19.6 (± 15.78)		
ALT, Week 24, n=261, 268	23.9 (± 31.14)	19.1 (± 11.91)		
ALT, Week 28, n=253, 268	22.5 (± 19.78)	19.6 (± 10.73)		
ALT, Week 32, n=256, 268	38.5 (± 293.55)	19.0 (± 11.56)		
ALT, Week 36, n=255, 261	20.3 (± 13.92)	21.2 (± 31.68)		
ALT, Week 40, n=250, 266	20.9 (± 17.32)	19.5 (± 12.35)		
ALT, Week 44, n=258, 263	22.2 (± 27.14)	19.8 (± 17.43)		
ALT, Week 48, n=247, 262	20.1 (± 21.78)	19.7 (± 16.58)		
ALP, Baseline (Day 1), n=283, 283	66.5 (± 22.06)	67.1 (± 22.98)		
ALP, Week 4, n=281, 277	66.2 (± 19.56)	65.5 (± 17.07)		
ALP, Week 8, n=212, 278	66.8 (± 18.82)	66.3 (± 17.49)		
ALP, Week 12, n=270, 276	66.8 (± 19.80)	66.1 (± 17.23)		
ALP, Week 16, n=255, 269	66.7 (± 19.96)	66.1 (± 17.89)		
ALP, Week 20, n=260, 272	67.6 (± 19.11)	65.6 (± 16.71)		
ALP, Week 24, n=261, 268	67.1 (± 19.68)	66.1 (± 17.96)		
ALP, Week 28, n=253, 268	67.4 (± 20.05)	67.5 (± 18.07)		
ALP, Week 32, n=256, 268	68.0 (± 22.17)	66.6 (± 17.65)		
ALP, Week 36, n=255, 261	69.5 (± 26.86)	68.3 (± 20.19)		
ALP, Week 40, n=250, 266	67.4 (± 18.94)	67.7 (± 18.30)		
ALP, Week 44, n=258, 263	67.7 (± 18.59)	68.2 (± 18.62)		
ALP, Week 48, n=247, 262	66.4 (± 17.95)	67.7 (± 18.15)		
AST, Baseline (Day 1), n=283, 283	28.8 (± 90.66)	22.5 (± 14.80)		
AST, Week 4, n=281, 277	25.1 (± 32.67)	20.9 (± 8.47)		
AST, Week 8, n=212, 278	23.6 (± 20.85)	20.5 (± 6.26)		
AST, Week 12, n=270, 276	22.8 (± 10.38)	21.0 (± 8.14)		
AST, Week 16, n=255, 269	23.0 (± 10.71)	22.8 (± 14.03)		
AST, Week 20, n=260, 272	25.3 (± 32.64)	22.7 (± 23.48)		
AST, Week 24, n=261, 268	25.9 (± 25.16)	21.2 (± 9.73)		
AST, Week 28, n=253, 268	24.8 (± 16.50)	21.7 (± 10.61)		
AST, Week 32, n=256, 268	37.1 (± 233.23)	20.7 (± 6.42)		
AST, Week 36, n=255, 261	23.0 (± 12.44)	22.4 (± 17.37)		
AST, Week 40, n=250, 266	23.1 (± 12.22)	21.0 (± 6.51)		
AST, Week 44, n=258, 263	24.4 (± 15.66)	21.9 (± 13.25)		
AST Week 48, n=247, 262	22.3 (± 10.98)	23.5 (± 42.49)		
CK, Baseline (Day 1), n=283, 283	197.8 (± 291.21)	199.8 (± 482.84)		
CK, Week 4, n=280, 277	230.2 (± 447.94)	173.0 (± 220.54)		
CK, Week 8, n=212, 278	258.0 (± 928.82)	152.9 (± 146.05)		

CK, Week 12, n=270, 276	201.8 (± 348.13)	182.6 (± 387.61)		
CK, Week 16, n=255, 269	179.7 (± 248.71)	234.0 (± 576.62)		
CK, Week 20, n=260, 272	215.7 (± 539.34)	258.9 (± 1109.04)		
CK, Week 24, n=261, 268	248.6 (± 628.44)	183.1 (± 368.02)		
CK, Week 28, n=253, 268	252.7 (± 673.98)	194.5 (± 506.24)		
CK, Week 32, n=256, 268	175.8 (± 223.16)	160.0 (± 176.09)		
CK, Week 36, n=254, 261	219.0 (± 507.30)	215.2 (± 460.38)		
CK, Week 40, n=250, 266	220.5 (± 507.68)	149.5 (± 115.14)		
CK, Week 44, n=258, 263	254.0 (± 477.19)	181.9 (± 428.28)		
CK, Week 48, n=247, 262	185.5 (± 227.54)	323.6 (± 2637.27)		

Notes:

[35] - Safety Population

[36] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameter over time including Week 48: Albumin

End point title	Absolute values for clinical chemistry parameter over time including Week 48: Albumin

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-albumin at indicated timepoints. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[37]	283[38]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=283, 283	43.8 (± 3.04)	44.1 (± 2.80)		
Week 4, n=280, 277	43.7 (± 3.03)	43.8 (± 2.70)		
Week 8, n=212, 278	43.5 (± 2.85)	43.9 (± 2.76)		
Week 12, n=270, 276	43.7 (± 3.06)	44.1 (± 2.87)		
Week 16, n=255, 269	44.1 (± 2.99)	44.0 (± 2.78)		
Week 20, n=260, 272	44.1 (± 3.11)	43.9 (± 2.72)		
Week 24, n=261, 268	44.3 (± 3.08)	44.2 (± 2.60)		
Week 28, n=253, 268	44.4 (± 3.09)	44.5 (± 2.66)		

Week 32, n=255, 268	44.6 (± 3.17)	44.4 (± 2.76)		
Week 36, n=254, 261	44.1 (± 3.05)	44.3 (± 2.63)		
Week 40, n=250, 266	44.8 (± 3.02)	44.5 (± 2.76)		
Week 44, n=258, 263	44.7 (± 2.98)	44.4 (± 2.71)		
Week 48, n=247, 262	44.6 (± 2.98)	44.6 (± 2.86)		

Notes:

[37] - Safety Population

[38] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters over time including Week 48: bilirubin, direct bilirubin and creatinine

End point title	Absolute values for clinical chemistry parameters over time including Week 48: bilirubin, direct bilirubin and creatinine

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including bilirubin, creatinine and direct bilirubin at indicated timepoints. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[39]	283[40]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin, Baseline (Day 1), n=283, 283	9.3 (± 5.12)	9.4 (± 4.68)		
Bilirubin, Week 4, n=281, 277	10.7 (± 6.37)	8.9 (± 4.40)		
Bilirubin, Week 8, n=212, 278	10.1 (± 4.62)	8.8 (± 3.85)		
Bilirubin, Week 12, n=270, 276	10.5 (± 5.45)	8.6 (± 3.53)		
Bilirubin, Week 16, n=255, 269	10.6 (± 5.49)	8.7 (± 3.74)		
Bilirubin, Week 20, n=260, 272	10.3 (± 5.29)	8.5 (± 3.40)		
Bilirubin, Week 24, n=261, 268	10.0 (± 5.09)	8.9 (± 3.86)		
Bilirubin, Week 28, n=253, 268	10.4 (± 5.67)	8.6 (± 3.90)		
Bilirubin, Week 32, n=256, 268	10.5 (± 7.86)	8.7 (± 3.95)		
Bilirubin, Week 36, n=255, 260	9.9 (± 6.35)	8.5 (± 3.42)		
Bilirubin, Week 40, n=250, 266	10.2 (± 5.26)	8.5 (± 3.52)		
Bilirubin, Week 44, n=258, 263	10.3 (± 5.15)	8.8 (± 3.78)		
Bilirubin, Week 48, n=247, 262	10.3 (± 5.23)	8.9 (± 3.71)		
Direct bilirubin, Baseline (Day 1), n=283, 283	2.3 (± 1.32)	2.2 (± 1.09)		
Direct bilirubin, Week 4, n=277, 277	2.4 (± 1.47)	2.1 (± 1.08)		
Direct bilirubin, Week 8, n=212, 278	2.4 (± 1.17)	2.1 (± 0.93)		
Direct bilirubin, Week 12, n=269, 273	2.5 (± 1.26)	2.1 (± 0.91)		
Direct bilirubin, Week 16, n=254, 268	2.4 (± 1.46)	2.1 (± 0.95)		
Direct bilirubin, Week 20, n=260, 272	2.4 (± 1.54)	2.1 (± 0.90)		

Direct bilirubin, Week 24, n=260, 266	2.3 (± 1.20)	2.1 (± 0.96)		
Direct bilirubin, Week 28, n=253, 268	2.5 (± 1.29)	2.1 (± 0.94)		
Direct bilirubin, Week 32, n=256, 268	2.5 (± 3.48)	2.1 (± 0.94)		
Direct bilirubin, Week 36, n=255, 260	2.4 (± 2.24)	2.0 (± 0.89)		
Direct bilirubin, Week 40, n=249, 266	2.3 (± 1.29)	2.1 (± 0.98)		
Direct bilirubin, Week 44, n=258, 263	2.4 (± 1.34)	2.1 (± 0.95)		
Direct bilirubin, Week 48, n=247, 262	2.3 (± 1.26)	2.2 (± 1.00)		
Creatinine, Baseline (Day 1), n=283, 283	89.00 (± 16.061)	85.80 (± 15.660)		
Creatinine, Week 4, n=280, 277	82.99 (± 15.599)	86.43 (± 14.655)		
Creatinine, Week 8, n=212, 278	79.50 (± 14.103)	85.50 (± 15.925)		
Creatinine, Week 12, n=270, 276	79.25 (± 14.433)	84.63 (± 15.155)		
Creatinine, Week 16, n=255, 269	79.58 (± 14.509)	85.18 (± 14.997)		
Creatinine, Week 20, n=261, 272	78.50 (± 13.966)	85.02 (± 15.488)		
Creatinine, Week 24, n=262, 268	79.10 (± 15.340)	85.05 (± 14.690)		
Creatinine, Week 28, n=253, 268	78.79 (± 14.741)	84.38 (± 15.023)		
Creatinine, Week 32, n=255, 268	78.89 (± 14.558)	84.50 (± 15.047)		
Creatinine, Week 36, n=254, 262	79.58 (± 14.973)	84.75 (± 14.352)		
Creatinine, Week 40, n=250, 266	79.50 (± 15.615)	84.70 (± 14.808)		
Creatinine, Week 44, n=258, 263	80.04 (± 15.401)	83.90 (± 14.604)		
Creatinine, Week 48, n=247, 262	79.95 (± 15.613)	90.88 (± 87.655)		

Notes:

[39] - Safety Population

[40] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters: total carbon-dioxide (CO2), chloride, glucose, phosphate, potassium, sodium and urea over time including Week 48

End point title	Absolute values for clinical chemistry parameters: total carbon-dioxide (CO2), chloride, glucose, phosphate, potassium, sodium and urea over time including Week 48

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters which includes total CO2, chloride, glucose, phosphate, potassium, sodium and urea at indicated timepoints. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[41]	283[42]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
CO2, Baseline (Day 1), n=283, 283	22.4 (± 2.24)	22.4 (± 2.10)		
CO2, Week 4, n=280, 276	23.0 (± 2.29)	22.6 (± 2.28)		
CO2, Week 8, n=212, 278	22.8 (± 2.07)	22.3 (± 2.27)		
CO2, Week 12, n=270, 276	22.6 (± 2.50)	22.2 (± 2.34)		
CO2, Week 16, n=255, 269	22.9 (± 2.40)	22.3 (± 2.50)		
CO2, Week 20, n=260, 272	22.8 (± 2.30)	22.4 (± 2.32)		
CO2, Week 24, n=261, 268	23.0 (± 2.71)	22.8 (± 2.19)		
CO2, Week 28, n=253, 268	23.0 (± 2.31)	22.8 (± 2.47)		
CO2, Week 32, n=255, 268	23.0 (± 2.31)	22.7 (± 2.35)		
CO2, Week 36, n=253, 261	23.1 (± 2.37)	22.5 (± 2.26)		
CO2, Week 40, n=249, 265	22.8 (± 2.34)	22.6 (± 2.39)		
CO2, Week 44, n=257, 263	22.9 (± 2.34)	22.4 (± 2.12)		
CO2, Week 48, n=247, 262	22.5 (± 2.18)	22.3 (± 2.04)		
Chloride, Baseline (Day 1), n=283, 283	104.6 (± 2.32)	104.3 (± 2.32)		
Chloride, Week 4, n=280, 277	104.6 (± 2.22)	104.7 (± 2.13)		
Chloride, Week 8, n=212, 278	104.7 (± 1.96)	104.6 (± 2.32)		
Chloride, Week 12, n=270, 276	104.6 (± 2.16)	104.7 (± 2.35)		
Chloride, Week 16, n=255, 269	104.4 (± 2.31)	104.7 (± 2.24)		
Chloride, Week 20, n=260, 272	104.3 (± 2.28)	104.7 (± 2.06)		
Chloride, Week 24, n=261, 268	104.4 (± 2.33)	104.5 (± 2.42)		
Chloride, Week 28, n=253, 268	104.5 (± 2.20)	104.5 (± 2.28)		
Chloride, Week 32, n=255, 268	104.4 (± 2.46)	104.5 (± 2.33)		
Chloride, Week 36, n=254, 261	104.4 (± 2.42)	104.7 (± 2.20)		
Chloride, Week 40, n=250, 266	104.8 (± 2.55)	104.7 (± 2.25)		
Chloride, Week 44, n=258, 263	104.7 (± 2.19)	105.0 (± 2.22)		
Chloride, Week 48, n=247, 262	104.7 (± 2.21)	104.7 (± 2.28)		
Glucose, Baseline (Day 1), n=283, 283	5.21 (± 1.632)	5.17 (± 0.932)		
Glucose, Week 4, n=236, 230	5.27 (± 1.322)	5.23 (± 0.734)		
Glucose, Week 8, n=172, 227	5.31 (± 1.347)	5.19 (± 0.644)		
Glucose, Week 12, n=229, 216	5.26 (± 0.911)	5.27 (± 0.616)		
Glucose, Week 16, n=204, 213	5.36 (± 1.804)	5.28 (± 0.801)		
Glucose, Week 20, n=209, 218	5.32 (± 0.735)	5.26 (± 0.634)		
Glucose, Week 24, n=221, 214	5.35 (± 1.219)	5.21 (± 0.634)		
Glucose, Week 28, n=207, 211	5.35 (± 1.633)	5.23 (± 0.614)		
Glucose, Week 32, n=201, 213	5.44 (± 1.355)	5.27 (± 0.600)		
Glucose, Week 36, n=199, 204	5.35 (± 0.797)	5.31 (± 0.960)		
Glucose, Week 40, n=203, 202	5.44 (± 1.319)	5.35 (± 0.753)		
Glucose, Week 44, n=208, 202	5.34 (± 0.991)	5.35 (± 0.709)		
Glucose, Week 48, n=248, 251	5.22 (± 0.895)	5.22 (± 0.690)		
Phosphate, Baseline (Day 1), n=283, 283	1.103 (± 0.1747)	1.097 (± 0.1765)		
Phosphate, Week 4, n=279, 277	1.137 (± 0.1774)	1.112 (± 0.1850)		

Phosphate, Week 8, n=212, 278	1.096 (± 0.1742)	1.114 (± 0.1858)		
Phosphate, Week 12, n=270, 276	1.097 (± 0.1802)	1.106 (± 0.1876)		
Phosphate, Week 16, n=255, 269	1.104 (± 0.1806)	1.119 (± 0.1823)		
Phosphate, Week 20, n=260, 272	1.078 (± 0.1843)	1.114 (± 0.1812)		
Phosphate, Week 24, n=261, 268	1.106 (± 0.1797)	1.109 (± 0.1791)		
Phosphate, Week 28, n=253, 268	1.094 (± 0.1814)	1.119 (± 0.1893)		
Phosphate, Week 32, n=255, 268	1.105 (± 0.1769)	1.104 (± 0.1945)		
Phosphate, Week 36, n=254, 261	1.102 (± 0.1862)	1.122 (± 0.1872)		
Phosphate, Week 40, n=250, 266	1.093 (± 0.1699)	1.114 (± 0.1837)		
Phosphate, Week 44, n=258, 263	1.096 (± 0.1851)	1.120 (± 0.1903)		
Phosphate, Week 48, n=247, 262	1.096 (± 0.1888)	1.120 (± 0.2341)		
Potassium, Baseline (Day 1), n=283, 283	4.12 (± 0.301)	4.14 (± 0.288)		
Potassium, Week 4, n=280, 277	4.27 (± 0.308)	4.20 (± 0.327)		
Potassium, Week 8, n=212, 278	4.22 (± 0.302)	4.22 (± 0.343)		
Potassium, Week 12, n=270, 276	4.21 (± 0.305)	4.19 (± 0.282)		
Potassium, Week 16, n=255, 269	4.21 (± 0.283)	4.18 (± 0.303)		
Potassium, Week 20, n=260, 272	4.21 (± 0.320)	4.19 (± 0.313)		
Potassium, Week 24, n=261, 268	4.24 (± 0.322)	4.21 (± 0.312)		
Potassium, Week 28, n=253, 268	4.20 (± 0.298)	4.23 (± 0.294)		
Potassium, Week 32, n=255, 268	4.21 (± 0.295)	4.21 (± 0.315)		
Potassium, Week 36, n=254, 261	4.21 (± 0.314)	4.22 (± 0.314)		
Potassium, Week 40, n=250, 266	4.19 (± 0.301)	4.20 (± 0.305)		
Potassium, Week 44, n=258, 263	4.21 (± 0.302)	4.21 (± 0.324)		
Potassium, Week 48, n=247, 262	4.13 (± 0.288)	4.17 (± 0.449)		
Sodium, Baseline (Day 1), n=283, 283	139.2 (± 1.89)	139.2 (± 1.76)		
Sodium, Week 4, n=280, 277	139.5 (± 1.98)	139.4 (± 1.83)		
Sodium, Week 8, n=212, 278	139.4 (± 1.78)	139.3 (± 1.86)		
Sodium, Week 12, n=270, 276	139.5 (± 1.80)	139.3 (± 1.84)		
Sodium, Week 16, n=255, 269	139.4 (± 1.76)	139.4 (± 1.94)		
Sodium, Week 20, n=260, 272	139.4 (± 1.75)	139.5 (± 1.77)		
Sodium, Week 24, n=261, 268	139.3 (± 1.82)	139.4 (± 1.95)		
Sodium, Week 28, n=253, 268	139.4 (± 1.80)	139.5 (± 1.83)		
Sodium, Week 32, n=255, 268	139.4 (± 1.83)	139.4 (± 1.72)		
Sodium, Week 36, n=254, 261	139.3 (± 1.87)	139.5 (± 1.70)		
Sodium, Week 40, n=250, 266	139.3 (± 2.04)	139.5 (± 1.84)		
Sodium, Week 44, n=258, 263	139.5 (± 1.95)	139.6 (± 1.79)		
Sodium, Week 48, n=247, 262	139.4 (± 1.68)	139.5 (± 1.75)		
Urea, Baseline (Day 1), n=283, 283	5.30 (± 1.468)	5.17 (± 1.458)		
Urea, Week 4, n=280, 277	5.33 (± 1.424)	5.14 (± 1.508)		
Urea, Week 8, n=212, 278	5.32 (± 1.485)	5.12 (± 1.480)		
Urea, Week 12, n=270, 276	5.28 (± 1.424)	5.20 (± 1.574)		
Urea, Week 16, n=255, 269	5.26 (± 1.385)	5.20 (± 1.561)		
Urea, Week 20, n=260, 272	5.18 (± 1.349)	5.22 (± 1.483)		
Urea, Week 24, n=261, 268	5.38 (± 1.489)	5.11 (± 1.449)		

Urea, Week 28, n=253, 268	5.32 (± 1.422)	5.21 (± 1.406)		
Urea, Week 32, n=255, 268	5.43 (± 1.440)	5.17 (± 1.491)		
Urea, Week 36, n=254, 261	5.31 (± 1.396)	5.23 (± 1.556)		
Urea, Week 40, n=250, 266	5.40 (± 1.523)	5.26 (± 1.566)		
Urea, Week 44, n=258, 263	5.38 (± 1.543)	5.24 (± 1.512)		
Urea, Week 48, n=247, 262	5.37 (± 1.402)	5.27 (± 2.305)		

Notes:

[41] - Safety Population

[42] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameter over time including Week 48: Lipase

End point title	Absolute values for clinical chemistry parameter over time including Week 48: Lipase

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-lipase at indicated timepoints. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[43]	283[44]		
Units: Units per liter				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=283, 283	31.0 (± 21.04)	30.9 (± 28.89)		
Week 4, n=278, 276	31.7 (± 27.17)	32.6 (± 24.73)		
Week 8, n=211, 278	31.5 (± 21.15)	31.3 (± 19.96)		
Week 12, n=270, 276	31.4 (± 23.94)	33.6 (± 23.37)		
Week 16, n=254, 269	30.8 (± 22.39)	32.1 (± 18.99)		
Week 20, n=260, 270	31.3 (± 23.46)	31.9 (± 19.13)		
Week 24, n=260, 268	31.3 (± 22.60)	32.2 (± 21.08)		
Week 28, n=253, 268	30.3 (± 18.71)	33.0 (± 22.56)		
Week 32, n=254, 268	33.5 (± 35.38)	33.2 (± 32.95)		
Week 36, n=254, 261	31.5 (± 20.49)	31.2 (± 20.03)		
Week 40, n=250, 266	32.6 (± 27.07)	32.1 (± 22.19)		
Week 44, n=258, 263	36.3 (± 45.04)	33.0 (± 24.09)		
Week 48, n=247, 261	30.1 (± 20.31)	32.6 (± 28.96)		

Notes:

[43] - Safety Population

[44] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameter over time including Week 48: Creatinine clearance.

End point title	Absolute values for clinical chemistry parameter over time including Week 48: Creatinine clearance.

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-creatinine clearance at indicated timepoints. Glomerular filtration rate (GFR) will be estimated by the central laboratory using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[45]	283[46]		
Units: mL/min/1.73/m^2				
arithmetic mean (standard deviation)				
Baseline (Day 1), n=283, 283	94.3 (± 17.61)	97.9 (± 17.70)		
Week 4, n=278, 277	101.2 (± 16.56)	96.5 (± 17.14)		
Week 8, n=211, 278	104.9 (± 15.64)	98.1 (± 17.46)		
Week 12, n=270, 276	104.8 (± 16.08)	98.6 (± 17.77)		
Week 16, n=254, 269	104.2 (± 15.03)	97.6 (± 16.84)		
Week 20, n=261, 271	105.5 (± 15.19)	98.0 (± 17.67)		
Week 24, n=261, 268	105.1 (± 16.05)	97.9 (± 17.33)		
Week 28, n=253, 268	105.3 (± 16.18)	98.8 (± 17.40)		
Week 32, n=254, 268	105.1 (± 16.10)	98.8 (± 17.39)		
Week 36, n=254, 262	104.7 (± 15.88)	98.0 (± 16.60)		
Week 40, n=250, 266	104.3 (± 16.47)	98.3 (± 17.25)		
Week 44, n=258, 263	104.4 (± 16.73)	98.9 (± 16.67)		
Week 48, n=247, 261	103.6 (± 16.34)	96.9 (± 18.21)		

Notes:

[45] - Safety Population

[46] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for fasting lipid panel overtime including Week 48

End point title	Absolute values for fasting lipid panel overtime including Week 48

End point description:

Blood samples were collected at Baseline and at Week 48 to assess fasting lipids which included total cholesterol, high density lipoprotein (HDL)cholesterol, low density lipoprotein (LDL) cholesterol and triglycerides. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[47]	283[48]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Total Cholesterol, Baseline (Day 1), n=268, 275	4.44 (± 0.928)	4.42 (± 0.986)		
Total Cholesterol, Week 48, n=240, 239	4.65 (± 1.021)	4.46 (± 0.944)		
HDL cholesterol, Baseline (Day 1), n=268, 275	1.249 (± 0.3761)	1.302 (± 0.3851)		
HDL cholesterol, Week 48, n=240, 239	1.359 (± 0.4096)	1.376 (± 0.4335)		
LDL cholesterol, Baseline (Day 1), n=267, 275	2.557 (± 0.7991)	2.529 (± 0.7870)		
LDL cholesterol, Week 48, n=238, 237	2.697 (± 0.9158)	2.472 (± 0.7693)		
Triglycerides, Baseline (Day 1), n=268, 275	1.387 (± 0.9142)	1.294 (± 0.7392)		
Triglycerides, Week 48, n=240, 239	1.323 (± 0.9333)	1.341 (± 0.9059)		

Notes:

[47] - Safety Population

[48] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal urinalysis parameter over time including Week 48

End point title	Number of participants with abnormal urinalysis parameter over time including Week 48

End point description:

The dipstick test gives results in a semi-quantitative manner and results for urinalysis parameters (ketones, glucose, bilirubin, occult blood, nitrite and blood protein) can be read as positive, trace, 1+, 2+, 3+ and 4+ indicating proportional concentrations in the urine sample. The urine parameters were graded according to DAIDS scale where Grade 1 indicates mild (trace to 1+), Grade 2 indicates moderate (2+) and Grade 3 indicates severe (3+ or higher). Only participants with abnormal findings for urinalysis at any visit has been presented. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:
Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[49]	283[50]		
Units: Participants				
number (not applicable)				
Urine bilirubin,Baseline (Day 1),Trace, n=276, 276	0	0		
Urine bilirubin, Baseline (Day 1), 1+, n=276, 276	15	22		
Urine bilirubin, Baseline (Day 1), 2+, n=276, 276	0	1		
Urine bilirubin, Baseline (Day 1), 3+, n=276, 276	0	0		
Urine glucose, Baseline (Day 1), Trace, n=282, 282	0	1		
Urine glucose, Baseline (Day 1), 1+, n=282, 282	2	0		
Urine glucose, Baseline (Day 1), 2+, n=282, 282	0	0		
Urine glucose, Baseline (Day 1), 3+, n=282, 282	1	1		
Urine ketones, Baseline (Day 1), Trace, n=276, 276	30	29		
Urine ketones, Baseline (Day 1), 1+, n=276, 276	4	2		
Urine ketones, Baseline (Day 1), 2+, n=276, 276	0	1		
Urine ketones, Baseline (Day 1), 3+, n=276, 276	0	0		
Urine leukocyte esterase,Baseline,Trace,n=276, 276	22	21		
Urine leukocyte esterase, Baseline, 1+, n=276, 276	12	14		
Urine leukocyte esterase, Baseline, 2+, n=276, 276	9	9		
Urine leukocyte esterase, Baseline, 3+, n=276, 276	3	3		
Urine nitrite, Baseline, positive, n=276, 276	6	9		
Urine occult blood, Baseline, Trace, n=276, 276	13	9		
Urine occult blood, Baseline, 1+, n=276, 276	5	6		
Urine occult blood, Baseline, 2+, n=276, 276	6	3		
Urine occult blood, Baseline, 3+, n=276, 276	3	2		
Urine protein, Baseline, Trace, n=276, 276	25	20		
Urine protein, Baseline, 1+, n=276, 276	4	10		
Urine protein, Baseline, 2+, n=276, 276	3	7		
Urine protein, Baseline, 3+, n=276, 276	0	0		

Urine bilirubin, Week 4, Trace, n=278, 272	0	0		
Urine bilirubin, Week 4, 1+, n=278, 272	14	28		
Urine bilirubin, Week 4, 2+, n=278, 272	0	0		
Urine bilirubin, Week 4, 3+, n=278, 272	0	0		
Urine glucose, Week 4, Trace, n=278, 272	0	0		
Urine glucose, Week 4, 1+, n=278, 272	0	2		
Urine glucose, Week 4, 2+, n=278, 272	0	0		
Urine glucose, Week 4, 3+, n=278, 272	1	0		
Urine ketones, Week 4, Trace, n=278, 272	20	21		
Urine ketones, Week 4, 1+, n=278, 272	1	5		
Urine ketones, Week 4, 2+, n=278, 272	0	0		
Urine ketones, Week 4, 3+, n=278, 272	1	0		
Urine leukocyte esterase, Week 4, Trace,n=278, 272	19	23		
Urine leukocyte esterase, Week 4, 1+, n=278, 272	9	17		
Urine leukocyte esterase, Week 4, 2+, n=278, 272	6	6		
Urine leukocyte esterase, Week 4, 3+, n=278, 272	2	4		
Urine nitrite, Week 4, positive, n=278, 272	2	10		
Urine occult blood, Week 4, Trace, n=278, 272	11	13		
Urine occult blood, Week 4, 1+, n=278, 272	8	3		
Urine occult blood, Week 4, 2+, n=278, 272	5	1		
Urine occult blood, Week 4, 3+, n=278, 272	0	6		
Urine protein, Week 4, Trace, n=278, 272	12	24		
Urine protein, Week 4, 1+, n=278, 272	4	11		
Urine protein, Week 4, 2+, n=278, 272	1	3		
Urine protein, Week 4, 3+, n=278, 272	1	1		
Urine bilirubin, Week 24, Trace, n=195, 258	0	0		
Urine bilirubin, Week 24, 1+, n=195, 258	7	14		
, Urine bilirubin, Week 24, 2+, n=195, 258	0	0		
Urine bilirubin, Week 24, 3+, n=195, 258	0	0		
Urine glucose, Week 24, Trace, n=195, 258	0	0		
Urine glucose, Week 24, 1+, n=195, 258	0	0		
Urine glucose, Week 24, 2+, n=195, 258	1	0		
Urine glucose, Week 24, 3+, n=195, 258	1	1		
Urine ketones, Week 24, Trace, n=195, 258	13	9		
Urine ketones, Week 24, 1+, n=195, 258	0	2		
Urine ketones, Week 24, 2+, n=195, 258	0	0		

Urine ketones, Week 24, 3+, n=195, 258	0	0		
Urine leukocyte esterase,Week 24, Trace,n=195, 258	15	28		
Urine leukocyte esterase, Week 24, 1+, n=195, 258	8	12		
Urine leukocyte esterase, Week 24, 2+, n=195, 258	3	10		
Urine leukocyte esterase, Week 24, 3+, n=195, 258	1	3		
Urine nitrite, Week 24, positive, n=195, 258	4	5		
Urine occult blood, Week 24, Trace, n=195, 258	9	9		
Urine occult blood, Week 24, 1+, n=195, 258	3	8		
Urine occult blood, Week 24, 2+, n=195, 258	3	2		
Urine occult blood, Week 24, 3+, n=195, 258	1	3		
Urine protein, Week 24, Trace, n=195, 258	11	21		
Urine protein, Week 24, 1+, n=195, 258	4	7		
Urine protein, Week 24, 2+, n=195, 258	2	4		
Urine protein, Week 24, 3+, n=195, 258	0	1		
Urine bilirubin, Week 48, Trace, n=261, 259	0	0		
Urine bilirubin, Week 48, 1+, n=261, 259	9	12		
Urine bilirubin, Week 48, 2+, n=261, 259	0	0		
Urine bilirubin, Week 48, 3+, n=261, 259	0	1		
Urine glucose, Week 48, Trace, n=261, 259	0	0		
Urine glucose, Week 48, 1+, n=261, 259	1	0		
Urine glucose, Week 48, 2+, n=261, 259	0	0		
Urine glucose, Week 48, 3+, n=261, 259	2	0		
Urine ketones, Week 48, Trace, n=261, 259	12	13		
Urine ketones, Week 48, 1+, n=261, 259	0	4		
Urine ketones, Week 48, 2+, n=261, 259	0	0		
Urine ketones, Week 48, 3+, n=261, 259	0	0		
Urine leukocyte esterase, Week 48,Trace,n=261, 259	12	15		
Urine leukocyte esterase, Week 48, 1+, n=261, 259	5	10		
Urine leukocyte esterase, Week 48, 2+, n=261, 259	4	7		
Urine leukocyte esterase, Week 48, 3+, n=261, 259	2	2		
Urine nitrite, Week 48, positive, n=261, 259	2	6		
Urine occult blood, Week 48, Trace, n=261, 259	9	8		

Urine occult blood, Week 48, 1+, n=261, 259	4	6		
Urine occult blood, Week 48, 2+, n=261, 259	8	3		
Urine occult blood, Week 48, 3+, n=261, 259	1	0		
Urine protein, Week 48, Trace, n=261, 259	14	23		
Urine protein, Week 48, 1+, n=261, 259	5	8		
Urine protein, Week 48, 2+, n=261, 259	6	6		
Urine protein, Week 48, 3+, n=261, 259	0	0		

Notes:

[49] - Safety Population

[50] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with urine potential of hydrogen (pH) over time including Week 48

End point title	Number of participants with urine potential of hydrogen (pH) over time including Week 48

End point description:

Urine samples were collected for analysis of urine pH. pH is calculated on a scale of 0 to 14, values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH of less than 7 is acidic and a pH of greater than 7 is basic. Normal urine has a slightly acidic pH (5.0-6.0). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[51]	283[52]		
Units: Participants				
number (not applicable)				
Baseline (Day 1), pH=5, n=276, 276	36	32		
Baseline (Day 1), pH=5.5, n=276, 276	104	101		
Baseline (Day 1), pH=6, n=276, 276	66	62		
Baseline (Day 1), pH=6.5, n=276, 276	29	35		
Baseline (Day 1), pH=7, n=276, 276	27	27		
Baseline (Day 1), pH=7.5, n=276, 276	7	12		
Baseline (Day 1), pH=8, n=276, 276	4	4		
Baseline (Day 1), pH=8.5, n=276, 276	2	1		
Baseline (Day 1), pH>9.0, n=276, 276	1	2		
Week 4, pH=5, n=278, 272	33	41		
Week 4, pH=5.5, n=278, 272	83	81		
Week 4, pH=6, n=278, 272	68	71		
Week 4, pH=6.5, n=278, 272	48	36		

Week 4, pH=7, n=278, 272	25	22		
Week 4, pH=7.5, n=278, 272	10	12		
Week 4, pH=8, n=278, 272	5	5		
Week 4, pH=8.5, n=278, 272	6	1		
Week 4, pH>9.0, n=278, 272	0	3		
Week 24, pH=5, n=195, 258	42	50		
Week 24, pH=5.5, n=195, 258	55	78		
Week 24, pH=6, n=195, 258	47	51		
Week 24, pH=6.5, n=195, 258	19	46		
Week 24, pH=7, n=195, 258	22	16		
Week 24, pH=7.5, n=195, 258	4	13		
Week 24, pH=8, n=195, 258	3	2		
Week 24, pH=8.5, n=195, 258	3	1		
Week 24, pH>9.0, n=195, 258	0	1		
Week 48, pH=5, n=261, 259	54	57		
Week 48, pH=5.5, n=261, 259	81	77		
Week 48, pH=6, n=261, 259	50	61		
Week 48, pH=6.5, n=261, 259	30	27		
Week 48, pH=7, n=261, 259	24	18		
Week 48, pH=7.5, n=261, 259	14	10		
Week 48, pH=8, n=261, 259	5	4		
Week 48, pH=8.5, n=261, 259	2	3		
Week 48, pH>9.0, n=261, 259	1	2		

Notes:

[51] - Safety Population

[52] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets

End point title	Change from Baseline for hematology parameters: basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets

End point description:

Blood samples were collected for the analysis of hematology parameters including basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets at indicated timepoints. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[53]	283[54]		
Units: 10^9 cells per Liter				
arithmetic mean (standard deviation)				
Basophils, Week 4, n=277, 270	0.002 (± 0.0155)	0.002 (± 0.0155)		
Basophils, Week 8, n=210, 272	0.002 (± 0.0161)	0.001 (± 0.0153)		
Basophils, Week 12, n=267, 272	0.003 (± 0.0181)	0.001 (± 0.0157)		
Basophils, Week 16, n=247, 259	0.008 (± 0.0215)	0.006 (± 0.0227)		
Basophils, Week 20, n=247, 259	0.013 (± 0.0250)	0.010 (± 0.0271)		
Basophils, Week 24, n=256, 260	0.015 (± 0.0247)	0.014 (± 0.0269)		
Basophils, Week 28, n=239, 258	0.017 (± 0.0265)	0.016 (± 0.0251)		
Basophils, Week 32, n=246, 263	0.022 (± 0.0266)	0.017 (± 0.0227)		
Basophils, Week 36, n=250, 259	0.021 (± 0.0235)	0.018 (± 0.0249)		
Basophils, Week 40, n=244, 245	0.020 (± 0.0252)	0.019 (± 0.0243)		
Basophils, Week 44, n=249, 260	0.018 (± 0.0246)	0.018 (± 0.0265)		
Basophils, Week 48, n=239, 258	0.016 (± 0.0218)	0.016 (± 0.0243)		
Eosinophils, Week 4, n=277, 270	0.024 (± 0.1099)	0.013 (± 0.1220)		
Eosinophils, Week 8, n=210, 272	0.023 (± 0.1101)	0.009 (± 0.1075)		
Eosinophils, Week 12, n=267, 272	0.023 (± 0.1305)	0.018 (± 0.1082)		
Eosinophils, Week 16, n=247, 259	0.037 (± 0.1425)	0.022 (± 0.1262)		
Eosinophils, Week 20, n=247, 259	0.044 (± 0.1478)	0.027 (± 0.1288)		
Eosinophils, Week 24, n=256, 260	0.051 (± 0.1307)	0.030 (± 0.1124)		
Eosinophils, Week 28, n=239, 258	0.061 (± 0.1367)	0.037 (± 0.1393)		
Eosinophils, Week 32, n=246, 263	0.061 (± 0.1556)	0.029 (± 0.1158)		
Eosinophils, Week 36, n=250, 259	0.070 (± 0.1797)	0.030 (± 0.1303)		
Eosinophils, Week 40, n=244, 245	0.062 (± 0.1623)	0.035 (± 0.1155)		
Eosinophils, Week 44, n=249, 260	0.057 (± 0.1598)	0.038 (± 0.1410)		
Eosinophils, Week 48, n=239, 258	0.039 (± 0.1416)	0.030 (± 0.1183)		
Leukocytes, Week 4, n=279, 272	0.57 (± 1.404)	0.42 (± 1.383)		
Leukocytes, Week 8, n=211, 275	0.18 (± 1.278)	0.32 (± 1.374)		
Leukocytes, Week 12, n=270, 275	0.07 (± 1.402)	0.40 (± 1.465)		
Leukocytes, Week 16, n=252, 265	0.32 (± 1.641)	0.41 (± 1.621)		
Leukocytes, Week 20, n=254, 265	0.27 (± 1.505)	0.44 (± 1.480)		
Leukocytes, Week 24, n=258, 264	0.34 (± 1.581)	0.45 (± 1.725)		

Leukocytes, Week 28, n=244, 263	0.34 (± 1.713)	0.48 (± 1.551)		
Leukocytes, Week 32, n=253, 266	0.28 (± 1.726)	0.42 (± 1.748)		
Leukocytes, Week 36, n=252, 259	0.34 (± 1.549)	0.52 (± 1.789)		
Leukocytes, Week 40, n=246, 253	0.16 (± 1.497)	0.42 (± 1.614)		
Leukocytes, Week 44, n=256, 262	0.22 (± 1.732)	0.49 (± 1.626)		
Leukocytes, Week 48, n=243, 260	0.09 (± 1.455)	0.29 (± 1.520)		
Lymphocytes, Week 4, n=277, 270	0.198 (± 0.5156)	0.231 (± 0.5066)		
Lymphocytes, Week 8, n=210, 272	0.054 (± 0.4812)	0.155 (± 0.5088)		
Lymphocytes, Week 12, n=267, 272	0.012 (± 0.4632)	0.164 (± 0.5560)		
Lymphocytes, Week 16, n=247, 259	0.020 (± 0.4971)	0.158 (± 0.5246)		
Lymphocytes, Week 20, n=247, 259	0.030 (± 0.4889)	0.146 (± 0.5292)		
Lymphocytes, Week 24, n=256, 260	0.014 (± 0.5195)	0.148 (± 0.5716)		
Lymphocytes, Week 28, n=239, 258	0.021 (± 0.5389)	0.145 (± 0.5469)		
Lymphocytes, Week 32, n=246, 263	0.021 (± 0.5195)	0.129 (± 0.5812)		
Lymphocytes, Week 36, n=250, 259	0.028 (± 0.5261)	0.132 (± 0.5258)		
Lymphocytes, Week 40, n=244, 245	0.006 (± 0.5303)	0.054 (± 0.5106)		
Lymphocytes, Week 44, n=249, 260	-0.021 (± 0.6176)	0.098 (± 0.5139)		
Lymphocytes, Week 48, n=239, 258	-0.074 (± 0.5191)	0.039 (± 0.5936)		
Monocytes, Week 4, n=277, 270	0.038 (± 0.1269)	0.031 (± 0.1528)		
Monocytes, Week 8, n=210, 272	0.022 (± 0.1464)	0.013 (± 0.1600)		
Monocytes, Week 12, n=267, 272	0.016 (± 0.1234)	0.018 (± 0.1613)		
Monocytes, Week 16, n=247, 259	0.059 (± 0.1548)	0.035 (± 0.1618)		
Monocytes, Week 20, n=247, 259	0.070 (± 0.1583)	0.053 (± 0.1790)		
Monocytes, Week 24, n=256, 260	0.059 (± 0.1442)	0.070 (± 0.1599)		
Monocytes, Week 28, n=239, 258	0.086 (± 0.1584)	0.077 (± 0.1806)		
Monocytes, Week 32, n=246, 263	0.081 (± 0.1530)	0.088 (± 0.1841)		
Monocytes, Week 36, n=250, 259	0.084 (± 0.1685)	0.086 (± 0.1772)		
Monocytes, Week 40, n=244, 245	0.056 (± 0.1378)	0.076 (± 0.1651)		
Monocytes, Week 44, n=249, 260	0.062 (± 0.1522)	0.057 (± 0.1558)		
Monocytes, Week 48, n=239, 258	0.024 (± 0.1395)	0.031 (± 0.1389)		
Neutrophils, Week 4, n=277, 270	0.313 (± 1.3508)	0.130 (± 1.1869)		
Neutrophils, Week 8, n=210, 272	0.084 (± 1.1310)	0.125 (± 1.2775)		
Neutrophils, Week 12, n=267, 272	0.032 (± 1.3016)	0.185 (± 1.3016)		

Neutrophils, Week 16, n=247, 259	0.215 (± 1.5752)	0.211 (± 1.4233)		
Neutrophils, Week 20, n=247, 259	0.132 (± 1.4116)	0.217 (± 1.3130)		
Neutrophils, Week 24, n=256, 260	0.218 (± 1.4890)	0.217 (± 1.4694)		
Neutrophils, Week 28, n=239, 258	0.193 (± 1.5833)	0.221 (± 1.3274)		
Neutrophils, Week 32, n=246, 263	0.144 (± 1.5739)	0.175 (± 1.5009)		
Neutrophils, Week 36, n=250, 259	0.170 (± 1.3865)	0.243 (± 1.4938)		
Neutrophils, Week 40, n=244, 245	0.055 (± 1.4372)	0.259 (± 1.4739)		
Neutrophils, Week 44, n=249, 260	0.156 (± 1.5382)	0.273 (± 1.4445)		
Neutrophils, Week 48, n=239, 258	0.110 (± 1.3697)	0.201 (± 1.3169)		
Platelets, Week 4, n=278, 269	5.7 (± 29.10)	4.3 (± 31.11)		
Platelets, Week 8, n=207, 273	-0.9 (± 29.09)	2.2 (± 35.14)		
Platelets, Week 12, n=269, 271	0.8 (± 32.49)	6.2 (± 36.23)		
Platelets, Week 16, n=251, 263	1.6 (± 33.34)	9.3 (± 51.53)		
Platelets, Week 20, n=255, 264	7.6 (± 38.18)	13.4 (± 39.24)		
Platelets, Week 24, n=256, 261	6.5 (± 36.11)	14.4 (± 35.15)		
Platelets, Week 28, n=245, 258	8.6 (± 38.23)	18.4 (± 38.56)		
Platelets, Week 32, n=249, 262	7.9 (± 40.22)	14.6 (± 34.28)		
Platelets, Week 36, n=248, 259	12.1 (± 38.48)	18.6 (± 35.81)		
Platelets, Week 40, n=244, 254	8.2 (± 36.08)	17.7 (± 43.30)		
Platelets, Week 44, n=254, 261	9.4 (± 38.42)	19.3 (± 47.64)		
Platelets, Week 48, n=240, 255	7.7 (± 39.61)	16.4 (± 47.45)		

Notes:

[53] - Safety Population

[54] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: erythrocyte mean corpuscular volume

End point title	Change from Baseline for hematology parameters: erythrocyte mean corpuscular volume

End point description:

Blood samples were collected for the analysis of hematology parameter including erythrocyte mean corpuscular volume at indicated timepoints. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance phase dose of IP. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[55]	283[56]		
Units: Femtoliters				
arithmetic mean (standard deviation)				
Week 4, n=279, 273	-0.7 (± 1.66)	0.2 (± 1.56)		
Week 8, n=211, 275	-2.5 (± 2.33)	0.2 (± 2.06)		
Week 12, n=270, 275	-3.8 (± 2.49)	-0.3 (± 2.48)		
Week 16, n=254, 265	-5.1 (± 2.63)	-0.2 (± 2.65)		
Week 20, n=255, 267	-5.6 (± 2.72)	-0.5 (± 2.55)		
Week 24, n=259, 264	-5.6 (± 2.85)	-0.5 (± 2.58)		
Week 28, n=246, 265	-5.6 (± 2.97)	-0.9 (± 2.52)		
Week 32, n=254, 267	-5.3 (± 3.02)	-0.9 (± 2.55)		
Week 36, n=252, 261	-5.3 (± 3.00)	-0.6 (± 2.45)		
Week 40, n=246, 255	-4.8 (± 3.02)	-0.1 (± 2.64)		
Week 44, n=256, 262	-4.2 (± 3.12)	0.2 (± 2.81)		
Week 48, n=243, 260	-3.7 (± 3.12)	1.0 (± 2.93)		

Notes:

[55] - Safety Population

[56] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: erythrocytes

End point title	Change from Baseline for hematology parameters: erythrocytes

End point description:

Blood samples were collected for the analysis of hematology parameters including erythrocytes at indicated timepoints. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance phase dose of IP. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[57]	283[58]		
Units: 10^12 cells per Liter				
arithmetic mean (standard deviation)				
Week 4, n=279, 273	0.08 (± 0.226)	-0.03 (± 0.228)		
Week 8, n=211, 275	0.18 (± 0.249)	0.02 (± 0.239)		
Week 12, n=270, 275	0.23 (± 0.269)	0.01 (± 0.273)		
Week 16, n=254, 265	0.30 (± 0.263)	0.01 (± 0.255)		
Week 20, n=255, 267	0.31 (± 0.272)	-0.01 (± 0.242)		

Week 24, n=259, 264	0.31 (± 0.254)	0.02 (± 0.242)		
Week 28, n=246, 265	0.29 (± 0.248)	0.04 (± 0.259)		
Week 32, n=254, 267	0.25 (± 0.283)	0.01 (± 0.259)		
Week 36, n=252, 261	0.23 (± 0.263)	-0.01 (± 0.250)		
Week 40, n=246, 255	0.23 (± 0.246)	-0.01 (± 0.239)		
Week 44, n=256, 262	0.21 (± 0.234)	-0.06 (± 0.243)		
Week 48, n=243, 260	0.16 (± 0.264)	-0.06 (± 0.257)		

Notes:

[57] - Safety Population

[58] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: hematocrit

End point title	Change from Baseline for hematology parameters: hematocrit

End point description:

Blood samples were collected for the analysis of hematology parameters including hematocrit at indicated timepoints. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance phase dose of IP. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[59]	283[60]		
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Week 4, n=279, 273	0.0046 (± 0.02082)	-0.0013 (± 0.02213)		
Week 8, n=211, 275	0.0053 (± 0.02344)	0.0026 (± 0.02314)		
Week 12, n=270, 275	0.0040 (± 0.02383)	-0.0000 (± 0.02618)		
Week 16, n=254, 265	0.0035 (± 0.02338)	-0.0003 (± 0.02489)		
Week 20, n=255, 267	0.0024 (± 0.02335)	-0.0033 (± 0.02323)		
Week 24, n=259, 264	0.0021 (± 0.02299)	-0.0012 (± 0.02337)		
Week 28, n=246, 265	-0.0003 (± 0.02262)	-0.0001 (± 0.02460)		
Week 32, n=254, 267	-0.0017 (± 0.02607)	-0.0032 (± 0.02503)		

Week 36, n=252, 261	-0.0041 (± 0.02515)	-0.0032 (± 0.02407)		
Week 40, n=246, 255	-0.0014 (± 0.02461)	-0.0017 (± 0.02388)		
Week 44, n=256, 262	-0.0011 (± 0.02230)	-0.0045 (± 0.02328)		
Week 48, n=243, 260	-0.0027 (± 0.02571)	-0.0019 (± 0.02572)		

Notes:

[59] - Safety Population

[60] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: hemoglobin

End point title	Change from Baseline for hematology parameters: hemoglobin

End point description:

Blood samples were collected for the analysis of hematology parameter including hemoglobin at indicated timepoints. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[61]	283[62]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Week 4, n=279, 273	1.8 (± 6.59)	0.1 (± 6.47)		
Week 8, n=211, 275	1.9 (± 7.29)	1.3 (± 7.26)		
Week 12, n=270, 275	2.1 (± 7.47)	1.5 (± 8.28)		
Week 16, n=254, 265	2.9 (± 6.98)	1.4 (± 7.88)		
Week 20, n=255, 267	2.9 (± 7.43)	1.4 (± 7.18)		
Week 24, n=259, 264	2.7 (± 7.32)	2.0 (± 7.11)		
Week 28, n=246, 265	2.7 (± 6.80)	3.3 (± 7.75)		
Week 32, n=254, 267	2.7 (± 8.08)	2.9 (± 7.73)		
Week 36, n=252, 261	2.0 (± 7.93)	2.8 (± 7.73)		
Week 40, n=246, 255	3.2 (± 7.91)	3.1 (± 7.85)		
Week 44, n=256, 262	2.5 (± 7.66)	1.8 (± 7.62)		
Week 48, n=243, 260	1.4 (± 7.98)	2.1 (± 8.33)		

Notes:

[61] - Safety Population

[62] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters over time including Week 48: ALT, ALP, AST and CK

End point title	Change from Baseline in clinical chemistry parameters over time including Week 48: ALT, ALP, AST and CK

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including ALT, ALP, AST and CK. Baseline values is defined as the latest pre-treatment assessment with a non-missing value. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[63]	283[64]		
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT, Week 4, n=281, 277	3.7 (± 49.90)	-1.4 (± 11.14)		
ALT, Week 8, n=212, 278	1.0 (± 14.28)	-0.9 (± 11.86)		
ALT, Week 12, n=270, 276	1.0 (± 15.80)	-0.1 (± 13.27)		
ALT, Week 16, n=255, 269	1.2 (± 16.61)	1.5 (± 13.99)		
ALT, Week 20, n=260, 272	5.3 (± 72.80)	0.2 (± 17.04)		
ALT, Week 24, n=261, 268	3.3 (± 30.00)	-0.4 (± 12.75)		
ALT, Week 28, n=253, 268	1.9 (± 18.82)	0.2 (± 12.72)		
ALT, Week 32, n=256, 268	18.1 (± 293.85)	-0.4 (± 13.08)		
ALT, Week 36, n=255, 261	-0.1 (± 14.10)	1.7 (± 32.63)		
ALT, Week 40, n=250, 266	0.6 (± 17.42)	0.0 (± 14.84)		
ALT, Week 44, n=258, 263	1.7 (± 27.55)	0.8 (± 16.75)		
ALT, Week 48, n=247, 262	-0.2 (± 22.91)	0.1 (± 18.81)		
ALP, Week 4, n=281, 277	0.3 (± 11.04)	-1.3 (± 15.74)		
ALP, Week 8, n=212, 278	0.6 (± 10.41)	-0.5 (± 17.00)		
ALP, Week 12, n=270, 276	1.4 (± 12.71)	-0.7 (± 17.40)		
ALP, Week 16, n=255, 269	0.8 (± 10.34)	-0.3 (± 17.99)		
ALP, Week 20, n=260, 272	1.5 (± 10.20)	-1.1 (± 17.35)		
ALP, Week 24, n=261, 268	1.2 (± 9.57)	-0.7 (± 17.03)		
ALP, Week 28, n=253, 268	1.4 (± 10.57)	0.6 (± 17.28)		
ALP, Week 32, n=256, 268	1.9 (± 15.42)	-0.3 (± 18.11)		
ALP, Week 36, n=255, 261	3.3 (± 20.31)	1.3 (± 20.90)		
ALP, Week 40, n=250, 266	1.8 (± 9.84)	0.7 (± 18.50)		
ALP, Week 44, n=258, 263	1.4 (± 11.00)	1.2 (± 17.62)		
ALP, Week 48, n=247, 262	1.1 (± 12.75)	0.7 (± 17.54)		
AST, Week 4, n=281, 277	1.5 (± 24.47)	-1.6 (± 14.58)		
AST, Week 8, n=212, 278	0.7 (± 19.90)	-2.0 (± 14.13)		
AST, Week 12, n=270, 276	-0.3 (± 10.74)	-1.5 (± 15.34)		

AST, Week 16, n=255, 269	-0.1 (± 11.31)	1.0 (± 16.68)		
AST, Week 20, n=260, 272	2.3 (± 32.28)	0.2 (± 26.46)		
AST, Week 24, n=261, 268	2.8 (± 24.22)	-1.5 (± 16.00)		
AST, Week 28, n=253, 268	1.7 (± 15.85)	-0.9 (± 16.99)		
AST, Week 32, n=256, 268	14.0 (± 233.48)	-1.9 (± 14.68)		
AST, Week 36, n=255, 261	-0.1 (± 12.22)	-0.2 (± 22.03)		
AST, Week 40, n=250, 266	0.2 (± 13.31)	-1.5 (± 15.24)		
AST, Week 44, n=258, 263	1.3 (± 16.49)	-0.5 (± 18.31)		
AST Week 48, n=247, 262	-0.8 (± 11.88)	0.8 (± 44.70)		
CK, Week 4, n=280, 277	31.1 (± 456.63)	-27.0 (± 523.89)		
CK, Week 8, n=212, 278	53.5 (± 907.83)	-46.6 (± 499.91)		
CK, Week 12, n=270, 276	1.2 (± 420.32)	-17.2 (± 605.92)		
CK, Week 16, n=255, 269	-18.0 (± 316.74)	40.2 (± 746.32)		
CK, Week 20, n=260, 272	19.2 (± 536.70)	57.3 (± 1208.73)		
CK, Week 24, n=261, 268	47.3 (± 635.42)	-19.6 (± 605.13)		
CK, Week 28, n=253, 268	49.9 (± 669.37)	-8.5 (± 705.35)		
CK, Week 32, n=256, 268	-24.5 (± 298.70)	-42.5 (± 509.77)		
CK, Week 36, n=254, 261	14.7 (± 515.62)	12.2 (± 674.76)		
CK, Week 40, n=250, 266	24.8 (± 544.72)	-51.7 (± 497.70)		
CK, Week 44, n=258, 263	54.8 (± 526.28)	-20.1 (± 652.24)		
CK, Week 48, n=247, 262	-17.8 (± 309.33)	121.1 (± 2682.33)		

Notes:

[63] - Safety Population

[64] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameter over time including Week 48: Albumin

End point title	Change from Baseline values for clinical chemistry parameter over time including Week 48: Albumin

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-albumin. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[65]	283[66]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Week 4, n=280, 277	-0.1 (± 2.15)	-0.3 (± 2.14)		
Week 8, n=212, 278	-0.1 (± 2.32)	-0.3 (± 2.25)		
Week 12, n=270, 276	-0.1 (± 2.38)	0.0 (± 2.58)		
Week 16, n=255, 269	0.2 (± 2.23)	-0.1 (± 2.48)		
Week 20, n=260, 272	0.2 (± 2.51)	-0.2 (± 2.47)		
Week 24, n=261, 268	0.5 (± 2.28)	0.2 (± 2.37)		
Week 28, n=253, 268	0.5 (± 2.42)	0.4 (± 2.32)		
Week 32, n=255, 268	0.7 (± 2.47)	0.4 (± 2.60)		
Week 36, n=254, 261	0.3 (± 2.44)	0.3 (± 2.52)		
Week 40, n=250, 266	0.9 (± 2.42)	0.5 (± 2.46)		
Week 44, n=258, 263	0.9 (± 2.44)	0.4 (± 2.49)		
Week 48, n=247, 262	0.7 (± 2.40)	0.5 (± 2.63)		

Notes:

[65] - Safety Population

[66] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters over time including Week 48: Bilirubin, direct bilirubin and creatinine

End point title	Change from Baseline values for clinical chemistry parameters over time including Week 48: Bilirubin, direct bilirubin and creatinine

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including bilirubin, creatinine and direct bilirubin. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[67]	283[68]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin, Week 4, n=281, 277	1.4 (± 4.74)	-0.3 (± 3.77)		
Bilirubin, Week 8, n=212, 278	0.9 (± 4.04)	-0.5 (± 4.17)		
Bilirubin, Week 12, n=270, 276	1.2 (± 4.15)	-0.7 (± 4.51)		
Bilirubin, Week 16, n=255, 269	1.2 (± 4.30)	-0.3 (± 3.61)		
Bilirubin, Week 20, n=260, 272	1.1 (± 4.14)	-0.7 (± 4.02)		
Bilirubin, Week 24, n=261, 268	0.8 (± 4.12)	-0.4 (± 3.85)		
Bilirubin, Week 28, n=253, 268	1.2 (± 4.41)	-0.7 (± 3.75)		
Bilirubin, Week 32, n=256, 268	1.3 (± 6.44)	-0.6 (± 4.05)		
Bilirubin, Week 36, n=255, 260	0.6 (± 5.36)	-0.7 (± 4.28)		
Bilirubin, Week 40, n=250, 266	0.9 (± 4.31)	-0.8 (± 4.32)		
Bilirubin, Week 44, n=258, 263	1.2 (± 4.34)	-0.4 (± 4.28)		
Bilirubin, Week 48, n=247, 262	1.1 (± 4.18)	-0.3 (± 4.17)		
Direct bilirubin, Week 4, n=277, 277	0.2 (± 1.40)	-0.1 (± 1.33)		
Direct bilirubin, Week 8, n=212, 278	0.2 (± 1.30)	-0.1 (± 1.19)		
Direct bilirubin, Week 12, n=269, 273	0.2 (± 1.22)	0.0 (± 1.22)		
Direct bilirubin, Week 16, n=254, 268	0.2 (± 1.44)	-0.1 (± 1.14)		
Direct bilirubin, Week 20, n=260, 272	0.2 (± 1.57)	-0.1 (± 1.14)		
Direct bilirubin, Week 24, n=260, 266	0.1 (± 1.46)	-0.1 (± 1.10)		
Direct bilirubin, Week 28, n=253, 268	0.2 (± 1.26)	-0.1 (± 1.22)		
Direct bilirubin, Week 32, n=256, 268	0.3 (± 3.39)	-0.1 (± 1.08)		
Direct bilirubin, Week 36, n=255, 260	0.1 (± 2.18)	-0.1 (± 1.16)		
Direct bilirubin, Week 40, n=249, 266	0.1 (± 1.42)	-0.1 (± 1.26)		
Direct bilirubin, Week 44, n=258, 263	0.2 (± 1.41)	-0.1 (± 1.19)		
Direct bilirubin, Week 48, n=247, 262	0.0 (± 1.41)	0.0 (± 1.19)		
Creatinine, Week 4, n=280, 277	-6.07 (± 9.696)	0.61 (± 7.635)		
Creatinine, Week 8, n=212, 278	-9.25 (± 9.936)	-0.24 (± 8.838)		
Creatinine, Week 12, n=270, 276	-9.89 (± 9.703)	-1.20 (± 8.710)		
Creatinine, Week 16, n=255, 269	-9.75 (± 9.572)	-0.33 (± 8.964)		
Creatinine, Week 20, n=261, 272	-10.10 (± 9.839)	-0.68 (± 8.700)		
Creatinine, Week 24, n=262, 268	-9.73 (± 9.499)	-0.75 (± 8.327)		
Creatinine, Week 28, n=253, 268	-10.34 (± 9.731)	-1.33 (± 8.892)		
Creatinine, Week 32, n=255, 268	-9.77 (± 9.166)	-1.26 (± 9.243)		
Creatinine, Week 36, n=254, 262	-9.57 (± 9.712)	-0.74 (± 8.565)		
Creatinine, Week 40, n=250, 266	-9.60 (± 10.656)	-1.10 (± 7.875)		
Creatinine, Week 44, n=258, 263	-9.02 (± 9.562)	-1.91 (± 8.306)		
Creatinine, Week 48, n=247, 262	-8.97 (± 9.742)	5.00 (± 85.535)		

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

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters over time including Week 48

End point title	Change from Baseline values for clinical chemistry parameters over time including Week 48

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters which includes total CO2, chloride, glucose, phosphate, potassium, sodium and urea. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[69]	283[70]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
CO2, Week 4, n=280, 276	0.6 (± 2.67)	0.2 (± 2.32)		
CO2, Week 8, n=212, 278	0.2 (± 2.51)	-0.1 (± 2.24)		
CO2, Week 12, n=270, 276	0.2 (± 2.56)	-0.1 (± 2.26)		
CO2, Week 16, n=255, 269	0.4 (± 2.55)	-0.1 (± 2.72)		
CO2, Week 20, n=260, 272	0.3 (± 2.52)	0.1 (± 2.38)		
CO2, Week 24, n=261, 268	0.6 (± 2.84)	0.4 (± 2.56)		
CO2, Week 28, n=253, 268	0.5 (± 2.51)	0.4 (± 2.39)		
CO2, Week 32, n=255, 268	0.5 (± 2.72)	0.3 (± 2.37)		
CO2, Week 36, n=253, 261	0.7 (± 2.54)	0.2 (± 2.35)		
CO2, Week 40, n=249, 265	0.4 (± 2.53)	0.2 (± 2.61)		
CO2, Week 44, n=257, 263	0.4 (± 2.71)	0.1 (± 2.37)		
CO2, Week 48, n=247, 262	0.0 (± 2.70)	0.0 (± 2.27)		
Chloride, Week 4, n=280, 277	0.0 (± 2.13)	0.5 (± 2.17)		
Chloride, Week 8, n=212, 278	0.0 (± 2.05)	0.3 (± 2.14)		
Chloride, Week 12, n=270, 276	0.0 (± 2.10)	0.4 (± 2.16)		
Chloride, Week 16, n=255, 269	-0.2 (± 2.32)	0.3 (± 2.39)		
Chloride, Week 20, n=260, 272	-0.3 (± 2.49)	0.4 (± 2.15)		
Chloride, Week 24, n=261, 268	-0.2 (± 2.40)	0.2 (± 2.47)		
Chloride, Week 28, n=253, 268	-0.2 (± 2.21)	0.1 (± 2.18)		

Chloride, Week 32, n=255, 268	-0.2 (± 2.37)	0.3 (± 2.34)		
Chloride, Week 36, n=254, 261	-0.1 (± 2.46)	0.4 (± 2.37)		
Chloride, Week 40, n=250, 266	0.1 (± 2.35)	0.4 (± 2.20)		
Chloride, Week 44, n=258, 263	0.1 (± 2.40)	0.7 (± 2.23)		
Chloride, Week 48, n=247, 262	0.0 (± 2.23)	0.3 (± 2.09)		
Phosphate, Week 4, n=279, 277	0.032 (± 0.1865)	0.014 (± 0.1771)		
Phosphate, Week 8, n=212, 278	-0.016 (± 0.1834)	0.017 (± 0.1855)		
Phosphate, Week 12, n=270, 276	-0.010 (± 0.1825)	0.009 (± 0.1772)		
Phosphate, Week 16, n=255, 269	0.000 (± 0.1789)	0.017 (± 0.1892)		
Phosphate, Week 20, n=260, 272	-0.029 (± 0.1932)	0.016 (± 0.1764)		
Phosphate, Week 24, n=261, 268	-0.001 (± 0.1907)	0.011 (± 0.1852)		
Phosphate, Week 28, n=253, 268	-0.007 (± 0.1894)	0.019 (± 0.1882)		
Phosphate, Week 32, n=255, 268	-0.004 (± 0.1806)	0.005 (± 0.2092)		
Phosphate, Week 36, n=254, 261	-0.006 (± 0.1798)	0.021 (± 0.1965)		
Phosphate, Week 40, n=250, 266	-0.011 (± 0.1851)	0.015 (± 0.1753)		
Phosphate, Week 44, n=258, 263	-0.004 (± 0.1824)	0.020 (± 0.1801)		
Phosphate, Week 48, n=247, 262	-0.007 (± 0.1784)	0.020 (± 0.2333)		
Potassium, Week 4, n=280, 277	0.15 (± 0.334)	0.06 (± 0.368)		
Potassium, Week 8, n=212, 278	0.10 (± 0.348)	0.08 (± 0.346)		
Potassium, Week 12, n=270, 276	0.09 (± 0.352)	0.05 (± 0.305)		
Potassium, Week 16, n=255, 269	0.10 (± 0.321)	0.04 (± 0.314)		
Potassium, Week 20, n=260, 272	0.09 (± 0.374)	0.04 (± 0.364)		
Potassium, Week 24, n=261, 268	0.12 (± 0.353)	0.07 (± 0.309)		
Potassium, Week 28, n=253, 268	0.08 (± 0.341)	0.08 (± 0.350)		
Potassium, Week 32, n=255, 268	0.09 (± 0.334)	0.06 (± 0.345)		
Potassium, Week 36, n=254, 261	0.10 (± 0.353)	0.08 (± 0.347)		
Potassium, Week 40, n=250, 266	0.07 (± 0.347)	0.06 (± 0.345)		
Potassium, Week 44, n=258, 263	0.08 (± 0.353)	0.06 (± 0.338)		
Potassium, Week 48, n=247, 262	0.01 (± 0.343)	0.03 (± 0.496)		
Sodium, Week 4, n=280, 277	0.3 (± 2.25)	0.2 (± 1.95)		
Sodium, Week 8, n=212, 278	0.1 (± 1.98)	0.1 (± 1.92)		
Sodium, Week 12, n=270, 276	0.3 (± 1.84)	0.1 (± 1.89)		
Sodium, Week 16, n=255, 269	0.2 (± 2.10)	0.3 (± 2.21)		
Sodium, Week 20, n=260, 272	0.2 (± 2.08)	0.4 (± 1.79)		
Sodium, Week 24, n=261, 268	0.2 (± 2.02)	0.2 (± 2.12)		
Sodium, Week 28, n=253, 268	0.2 (± 1.88)	0.4 (± 1.82)		
Sodium, Week 32, n=255, 268	0.3 (± 2.13)	0.3 (± 2.02)		
Sodium, Week 36, n=254, 261	0.2 (± 2.16)	0.4 (± 1.94)		
Sodium, Week 40, n=250, 266	0.1 (± 2.08)	0.4 (± 2.13)		
Sodium, Week 44, n=258, 263	0.3 (± 2.30)	0.4 (± 2.01)		
Sodium, Week 48, n=247, 262	0.2 (± 2.11)	0.3 (± 1.72)		
Urea, Week 4, n=280, 277	0.04 (± 1.292)	-0.05 (± 1.240)		

Urea, Week 8, n=212, 278	0.04 (± 1.315)	-0.05 (± 1.278)		
Urea, Week 12, n=270, 276	-0.01 (± 1.287)	0.04 (± 1.340)		
Urea, Week 16, n=255, 269	0.02 (± 1.394)	0.01 (± 1.171)		
Urea, Week 20, n=260, 272	-0.07 (± 1.359)	0.04 (± 1.190)		
Urea, Week 24, n=261, 268	0.09 (± 1.459)	-0.08 (± 1.154)		
Urea, Week 28, n=253, 268	0.02 (± 1.412)	0.02 (± 1.230)		
Urea, Week 32, n=255, 268	0.16 (± 1.364)	-0.03 (± 1.330)		
Urea, Week 36, n=254, 261	0.05 (± 1.451)	0.04 (± 1.265)		
Urea, Week 40, n=250, 266	0.07 (± 1.466)	0.05 (± 1.312)		
Urea, Week 44, n=258, 263	0.12 (± 1.361)	0.03 (± 1.290)		
Urea, Week 48, n=247, 262	0.09 (± 1.362)	0.06 (± 2.189)		

Notes:

[69] - Safety Population

[70] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameter over time including Week 48: Lipase

End point title	Change from Baseline values for clinical chemistry parameter over time including Week 48: Lipase

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-lipase. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[71]	283[72]		
Units: Units per liter				
arithmetic mean (standard deviation)				
Week 4, n=278, 276	1.6 (± 23.51)	1.8 (± 30.92)		
Week 8, n=211, 278	0.8 (± 19.07)	0.4 (± 27.41)		
Week 12, n=270, 276	1.3 (± 18.55)	2.5 (± 29.44)		
Week 16, n=254, 269	0.8 (± 20.27)	1.2 (± 27.24)		
Week 20, n=260, 270	1.6 (± 16.26)	0.8 (± 27.96)		
Week 24, n=260, 268	0.9 (± 18.74)	0.9 (± 27.58)		
Week 28, n=253, 268	-0.4 (± 16.73)	1.8 (± 29.09)		
Week 32, n=254, 268	2.9 (± 29.88)	2.0 (± 34.42)		
Week 36, n=254, 261	1.0 (± 17.45)	-0.1 (± 28.89)		

Week 40, n=250, 266	2.3 (± 22.71)	0.6 (± 27.95)		
Week 44, n=258, 263	5.7 (± 41.87)	1.6 (± 29.05)		
Week 48, n=247, 261	0.7 (± 16.14)	1.1 (± 32.35)		

Notes:

[71] - Safety Population

[72] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameter over time including Week 48: Creatinine clearance

End point title	Change from Baseline values for clinical chemistry parameter over time including Week 48: Creatinine clearance

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-creatinine clearance. GFR will be estimated by the central laboratory using the CKD-EPI. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[73]	283[74]		
Units: mL/min/1.73/m^2				
arithmetic mean (standard deviation)				
Week 4, n=278, 277	6.9 (± 10.16)	-1.2 (± 8.72)		
Week 8, n=211, 278	10.0 (± 11.83)	0.2 (± 9.13)		
Week 12, n=270, 276	10.7 (± 11.49)	0.9 (± 9.83)		
Week 16, n=254, 269	10.4 (± 11.28)	-0.3 (± 10.23)		
Week 20, n=261, 271	10.9 (± 11.45)	0.3 (± 9.90)		
Week 24, n=261, 268	10.5 (± 11.38)	0.2 (± 9.63)		
Week 28, n=253, 268	10.9 (± 11.90)	1.0 (± 9.90)		
Week 32, n=254, 268	10.6 (± 11.45)	1.1 (± 10.05)		
Week 36, n=254, 262	10.3 (± 11.94)	0.2 (± 10.08)		
Week 40, n=250, 266	10.2 (± 12.57)	0.7 (± 9.19)		
Week 44, n=258, 263	9.8 (± 11.61)	1.4 (± 9.88)		
Week 48, n=247, 261	9.5 (± 11.35)	-0.7 (± 10.86)		

Notes:

[73] - Safety Population

[74] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for fasting lipid panel and glucose overtime including Week 48

End point title	Change from Baseline values for fasting lipid panel and glucose overtime including Week 48

End point description:

Blood samples were collected at Baseline and at Week 48 to assess glucose and fasting lipids which included total cholesterol, high density lipoprotein (HDL)cholesterol, low density lipoprotein (LDL) cholesterol and triglycerides. Only fasting data is presented for glucose and lipids. Baseline value is defined as the last available fasting recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at Week 48 visit (if collected while fasting) minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[75]	283[76]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Glucose, Week 48, n=248, 251	0.02 (± 1.220)	0.04 (± 0.923)		
Total Cholesterol, Week 48, n=240, 239	0.09 (± 0.658)	0.05 (± 0.607)		
HDL cholesterol, Week 48, n=240, 239	0.109 (± 0.2587)	0.076 (± 0.2478)		
LDL cholesterol, Week 48, n=238, 237	0.122 (± 0.5807)	-0.045 (± 0.5384)		
Triglycerides, Week 48, n=240, 239	-0.085 (± 0.7167)	0.073 (± 0.8361)		

Notes:

[75] - Safety Population

[76] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine albumin/creatinine ratio and urine protein/creatinine ratio over time including Week 48

End point title	Change from Baseline values in urine albumin/creatinine ratio and urine protein/creatinine ratio over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine albumin/creatinine ratio and urine protein/creatinine ratio. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[77]	283[78]		
Units: Grams per mole				
arithmetic mean (standard deviation)				
Urine albumin/creatinine ratio, Week 4,n=199, 194	0.36 (± 6.714)	0.23 (± 4.062)		
Urine albumin/creatinine ratio, Week 24,n=137, 184	0.30 (± 4.941)	1.06 (± 7.186)		
Urine albumin/creatinine ratio, Week 48,n=181, 184	-0.53 (± 17.469)	0.19 (± 3.944)		
Urine protein/creatinine, Week 4, n=211, 215	-0.16 (± 18.641)	0.19 (± 6.439)		
Urine protein/creatinine, Week 24, n=151, 204	2.23 (± 35.187)	1.32 (± 12.171)		
Urine protein/creatinine, Week 48, n=194, 197	-1.86 (± 21.898)	0.26 (± 8.180)		

Notes:

[77] - Safety Population

[78] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine creatinine over time including Week 48

End point title	Change from Baseline values in urine creatinine over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine creatinine. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[79]	283[80]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Week 4, n=277, 272	-519.5 (± 9558.55)	-429.0 (± 9540.31)		
Week 24, n=193, 258	-597.4 (± 9405.95)	-17.1 (± 9575.04)		

Week 48, n=260, 258	-1359.2 (± 9059.43)	-505.4 (± 8873.05)		

Notes:

[79] - Safety Population

[80] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine phosphate over time including Week 48

End point title	Change from Baseline values in urine phosphate over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine phosphate. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[81]	283[82]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Week 4, n=275, 273	1.842 (± 18.4414)	-0.693 (± 18.4830)		
Week 24, n=192, 260	0.585 (± 19.2777)	-0.689 (± 16.9500)		
Week 48, n=259, 258	0.043 (± 17.3741)	0.304 (± 16.7073)		

Notes:

[81] - Safety Population

[82] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine retinol binding protein over time including Week 48

End point title	Change from Baseline values in urine retinol binding protein over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine retinol binding protein. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[83]	283[84]		
Units: Nanomoles per liter				
arithmetic mean (standard deviation)	-0.33 (± 0.938)	-0.24 (± 0.932)		

Notes:

[83] - Safety Population

[84] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine specific gravity over time including Week 48

End point title	Change from Baseline values in urine specific gravity over time including Week 48

End point description:

Urine biomarker samples were collected for the analysis of urine specific gravity. Urine specific gravity is a measure of the concentration of solutes in the urine and provides information on the kidney's ability to concentrate urine. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. The urine specific gravity was measured as the ratio of urine density compared with water density.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	283		
Units: Ratio of urine density to water density				
arithmetic mean (standard deviation)				
Week 4, n=271, 266	-0.0004 (± 0.00837)	-0.0005 (± 0.00798)		
Week 24, n=191, 252	-0.0001 (± 0.00805)	-0.0002 (± 0.00825)		
Week 48, n=255, 252	-0.0009 (± 0.00784)	-0.0007 (± 0.00783)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values in urine pH over time including Week 48

End point title	Change from Baseline values in urine pH over time including Week 48

End point description:

Urine samples were collected for analysis of urine pH. pH is calculated on a scale of 0 to 14, values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH of less than 7 is acidic and a pH of greater than 7 is basic. Normal urine has a slightly acidic pH (5.0-6.0). Baseline value is defined as the last available recorded value up to and including the date of first Maintenance Phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 4, 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[85]	283[86]		
Units: pH				
arithmetic mean (standard deviation)				
Week 4, n=271, 266	0.12 (± 0.833)	0.01 (± 0.884)		
Week 24, n=191, 252	-0.01 (± 0.889)	-0.07 (± 0.910)		
Week 48, n=255, 252	0.01 (± 0.926)	-0.10 (± 0.988)		

Notes:

[85] - Safety Population

[86] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who discontinued or withdrawn due to AEs over time including Week 48

End point title	Number of participants who discontinued or withdrawn due to AEs over time including Week 48

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. All Maintenance Phase adverse events (start date occurring on or after the date of first dose of randomized study treatment) leading to withdrawal have been presented.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[87]	283[88]		
Units: Participants	9	4		

Notes:

[87] - Safety Population

[88] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage change from Baseline in fasting lipids overtime including Week 48

End point title	Percentage change from Baseline in fasting lipids overtime including Week 48

End point description:

Blood samples were collected at Baseline and at Week 48 to assess fasting lipids which included total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides. Baseline value is defined as the last available recorded fasting value up to and including the date of first Maintenance Phase dose of IP. Percentage change from baseline is calculated as: value at Week 48 (if collected while fasting) minus Baseline value divided by Baseline value multiplied by 100. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[89]	283[90]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Cholesterol, Week 48, Overall, n=240, 239	5.09 (± 15.695)	2.32 (± 14.456)		
HDL cholesterol, Week 48, Overall, n=240, 239	15.448 (± 78.5208)	7.361 (± 20.3088)		
LDL cholesterol, Week 48, Overall, n=238, 237	7.048 (± 29.2139)	0.462 (± 23.9648)		
Triglycerides, Week 48, Overall, n=240, 239	2.633 (± 44.1663)	14.252 (± 62.2823)		

Notes:

[89] - Safety Population

[90] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with phenotypic resistance through Week 48

End point title	Number of participants with phenotypic resistance through Week 48

End point description:

Plasma samples were collected from participants who met confirmed virologic withdrawal criteria.Phenotypic Resistance data for drugs:CAB, DTG,elvitegravir (EVG), raltegravir(RAL),delavirdine(DLV),efavirenz(EFV),etravirine(ETR),nevirapine(NVP),RPV,3TC, ABC,emtricitabine(FTC),tenofovir(TDF),zidovudine(ZDV),stavudine(d4T),didanosine(ddI),atazanavir(ATV),darunavir(DRV),fosamprenavir(FPV),indinavir(IDV),lopinavir(LPV),nelfinavir(NFV),ritonavir(RTV), saquinavir(SQV) and tipranavir (TPV) is presented.Phenotypic resistance, partially sensitive, and Sensitive are based on fold change(FC) value from Monogram as:resistance(FC>clinical higher cutoff/biologic cutoff),partially sensitive (FC=clinical higher cutoff and > clinical lower cutoff),sensitive(FC<=clinical lower cutoff/biologic cutoff). CVF population comprised of participants in ITT-E population who met CVF criteria. Only participants with data available at specified data points

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3[91]	3[92]		
Units: Participants				
number (not applicable)				
INI, CAB, sensitive	0	3		
INI, CAB, partially sensitive	0	0		
INI, CAB, resistant	3	0		
INI, DTG, sensitive	3	3		
INI, DTG, partially sensitive	0	0		
INI, DTG, resistant	0	0		
INI, EVG, sensitive	0	3		
INI, EVG, partially sensitive	0	0		
INI, EVG, resistant	3	0		
INI, RAL, sensitive	0	3		
INI, RAL, partially sensitive	0	0		
INI, RAL, resistant	3	0		
NNRTI, DLV, sensitive	1	3		
NNRTI, DLV, partially sensitive	0	0		
NNRTI, DLV, resistant	2	0		
NNRTI, EFV, sensitive	1	3		
NNRTI, EFV, partially sensitive	0	0		
NNRTI, EFV, resistant	2	0		
NNRTI, ETR, sensitive	2	3		
NNRTI, ETR, partially sensitive	1	0		
NNRTI, ETR, resistant	0	0		
NNRTI, NVP, sensitive	1	3		
NNRTI, NVP, partially sensitive	0	0		
NNRTI, NVP, resistant	2	0		
NNRTI, RPV, sensitive	1	3		
NNRTI, RPV, partially sensitive	0	0		
NNRTI, RPV, resistant	2	0		
NRTI, 3TC, sensitive	3	3		
NRTI, 3TC, partially sensitive	0	0		
NRTI, 3TC, resistant	0	0		
NRTI, ABC, sensitive	3	3		

NRTI, ABC, partially sensitive	0	0		
NRTI, ABC, resistant	0	0		
NRTI, FTC, sensitive	3	0		
NRTI, FTC, partially sensitive	0	0		
NRTI, FTC, resistant	0	0		
NRTI, TDF, sensitive	1	3		
NRTI, TDF, partially sensitive	2	0		
NRTI, TDF, resistant	0	0		
NRTI, ZDV, sensitive	2	3		
NRTI, ZDV, partially sensitive	0	0		
NRTI, ZDV, resistant	1	0		
NRTI, d4T, sensitive	3	3		
NRTI, d4T, partially sensitive	0	0		
NRTI, d4T, resistant	0	0		
NRTI, ddI, sensitive	3	3		
NRTI, ddI, partially sensitive	0	0		
NRTI, ddI, resistant	0	0		
PI, ATV, sensitive	3	3		
PI, ATV, partially sensitive	0	0		
PI, ATV, resistant	0	0		
PI, DRV, sensitive	3	3		
PI, DRV, partially sensitive	0	0		
PI, DRV, resistant	0	0		
PI, FPV, sensitive	3	3		
PI, FPV, partially sensitive	0	0		
PI, FPV, resistant	0	0		
PI, IDV, sensitive	3	3		
PI, IDV, partially sensitive	0	0		
PI, IDV, resistant	0	0		
PI, LPV, sensitive	3	3		
PI, LPV, partially sensitive	0	0		
PI, LPV, resistant	0	0		
PI, NFV, sensitive	3	3		
PI, NFV, partially sensitive	0	0		
PI, NFV, resistant	0	0		
PI, RTV, sensitive	3	3		
PI, RTV, partially sensitive	0	0		
PI, RTV, resistant	0	0		
PI, SQV, sensitive	3	3		
PI, SQV, partially sensitive	0	0		
PI, SQV, resistant	0	0		
PI, TPV, sensitive	3	3		
PI, TPV, partially sensitive	0	0		
PI, TPV, resistant	0	0		

Notes:

[91] - CVF Population

[92] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with genotypic resistance through Week 48

End point title	Number of participants with genotypic resistance through Week 48

End point description:

Plasma samples were collected and analyzed from participants who met confirmed virologic withdrawal criteria. Genotypic Resistance data for the following drugs: DTG, EVG, RAL, DLV, EFV, ETR, NVP, RPV, 3TC, ABC, FTC, TDF, ZDV, d4T, ddI, ATV, DRV, FPV, IDV, LPV, NFV, RTV, SQV and TPV in participants meeting CVF criteria has been presented. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3[93]	3[94]		
Units: Participants				
number (not applicable)				
INI, DTG, resistant	0	0		
INI, DTG, resistance possible	2	0		
INI, DTG, sensitive	1	3		
INI, EVG, resistant	2	0		
INI, EVG, resistance possible	0	0		
INI, EVG, sensitive	1	3		
INI, RAL, resistant	2	0		
INI, RAL, resistance possible	0	0		
INI, RAL, sensitive	1	3		
NNRTI, DLV, resistant	0	0		
NNRTI, DLV, resistance possible	0	0		
NNRTI, DLV, sensitive	3	3		
NNRTI, EFV, resistant	0	0		
INI, EFV, resistance possible	1	0		
NNRTI, EFV, sensitive	2	3		
NNRTI, ETR, resistant	0	0		
NNRTI, ETR, resistance possible	0	0		
NNRTI, ETR, sensitive	3	3		
NNRTI, NVP, resistant	0	0		
NNRTI, NVP, resistance possible	1	0		
NNRTI, NVP, sensitive	2	3		
NNRTI, RPV, resistant	3	0		
NNRTI, RPV, resistance possible	0	0		
NNRTI, RPV, sensitive	0	3		
NRTI, 3TC, resistant	0	0		
NNRTI, 3TC, resistance possible	0	0		
NRTI, 3TC, sensitive	3	3		
NRTI, ABC, resistant	0	0		
NRTI, ABC, resistance possible	0	0		
NRTI, ABC, sensitive	3	3		
NRTI, FTC, resistant	0	0		

NRTI, FTC, resistance possible	0	0		
NRTI, FTC, sensitive	3	3		
NRTI, TDF, resistant	0	0		
NRTI, TDF, resistance possible	0	0		
NRTI, TDF, sensitive	3	3		
NRTI, ZDV, resistant	0	0		
NRTI, ZDV, resistance possible	0	0		
NRTI, ZDV, sensitive	3	3		
NRTI, d4T, resistant	0	0		
NRTI, d4T, resistance possible	0	0		
NRTI, d4T, sensitive	3	3		
NRTI, ddI, resistant	0	0		
NRTI, ddI, resistance possible	0	0		
NRTI, ddI, sensitive	3	3		
PI, ATV, resistant	0	0		
PI, ATV, resistance possible	0	0		
PI, ATV, sensitive	3	3		
PI, ATV/r, resistant	0	0		
PI, ATV/r, resistance possible	0	0		
PI, ATV/r, sensitive	3	3		
PI, DRV/r, resistant	0	0		
PI, DRV/r, resistance possible	0	0		
PI, DRV/r, sensitive	3	3		
PI, FPV/r, resistant	0	0		
PI, FPV/r, resistance possible	0	0		
PI, FPV/r, sensitive	3	3		
PI, IDV/r, resistant	0	0		
PI, IDV/r, resistance possible	0	0		
PI, IDV/r, sensitive	3	3		
PI, LPV/r, resistant	0	0		
PI, LPV/r, resistance possible	0	0		
PI, LPV/r, sensitive	3	3		
PI, NFV, resistant	0	0		
PI, NFV, resistance possible	0	0		
PI, NFV, sensitive	3	3		
PI, RTV, resistant	0	0		
PI, RTV, resistance possible	0	0		
PI, RTV, sensitive	3	3		
PI, SQV/r, resistant	0	0		
PI, SQV/r, resistance possible	0	0		
PI, SQV/r, sensitive	3	3		
PI, TPV/r, resistant	0	0		
PI, TPV/r, resistance possible	1	0		
PI, TPV/r, sensitive	2	3		

Notes:

[93] - CVF Population

[94] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the curve (AUC) for CAB LA

End point title	Area under the curve (AUC) for CAB LA

End point description:

AUC values are Bayesian pharmacokinetic (PK) parameter estimates obtained from a population PK meta-analysis of the data collected from studies 201584 and 201585# NCT02951052. Blood samples from the current study 201584 were collected at indicated time points to analyse concentration in plasma for CAB LA. The PK Population includes all participants who received CAB and / or RPV and undergo PK sampling during the study, and provide CAB and /or RPV plasma concentration data.

End point type	Secondary

End point timeframe:

Pre-dose at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48; 1 Week post-dose at Weeks 5, 41, 2 hours post-dose at Weeks 4 and 48

End point values	CAB LA			
Subject group type	Subject analysis set			
Number of subjects analysed	278[95]			
Units: Hours*micrograms per milliliter				
geometric mean (confidence interval 95%)	2517.40 (2439.876 to 2597.394)			

Notes:

[95] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma trough concentration (Ctrough) for CAB LA evaluable

End point title	Plasma trough concentration (Ctrough) for CAB LA evaluable

End point description:

Blood samples were collected at indicated time points for PK analysis of CAB LA. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Pre-dose at Weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48

End point values	CAB LA			
Subject group type	Subject analysis set			
Number of subjects analysed	278			
Units: Microgram per milliliter				
geometric mean (confidence interval 95%)				
Pre-dose, Week 8, n=250	1.5616 (1.4508 to 1.6808)			
Pre-dose, Week 12, n=237	2.0141 (1.8990 to 2.1362)			

Pre-dose, Week 16, n=215	2.0960 (1.9740 to 2.2255)			
Pre-dose, Week 20, n=233	2.1739 (2.0580 to 2.2963)			
Pre-dose, Week 24, n=227	2.3827 (2.2731 to 2.4976)			
Pre-dose, Week 28, n=220	2.4683 (2.3421 to 2.6013)			
Pre-dose, Week 32, n=219	2.6729 (2.5339 to 2.8196)			
Pre-dose, Week 36, n=215	2.8590 (2.7096 to 3.0165)			
Pre-dose, Week 40, n=210	2.9378 (2.7872 to 3.0966)			
Pre-dose, Week 44, n=217	3.0133 (2.8739 to 3.1595)			
Pre-dose, Week 48, n=197	3.1325 (2.9454 to 3.3315)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUC for RPV LA

End point title	AUC for RPV LA

End point description:

AUC values are Bayesian PK parameter estimates obtained from a population PK meta-analysis of the data collected from studies 201584 and 201585# NCT02951052. Blood samples from the current study 201584 were collected at indicated time points to analyse concentration in plasma for RPV LA.

End point type	Secondary

End point timeframe:

Pre-dose at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48; 1 Week post-dose at Weeks 5, 41, 2 hours post-dose at Weeks 4 and 48

End point values	RPV LA			
Subject group type	Subject analysis set			
Number of subjects analysed	278			
Units: Hours*nanograms per milliliter				
geometric mean (confidence interval 95%)	63989.13 (61489.692 to 66590.156)			

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough for RPV LA evaluable

End point title	Ctrough for RPV LA evaluable
End point description:	
Blood samples were collected at indicated time points for PK analysis of RPV LA. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).	
End point type	Secondary
End point timeframe:	
Pre-dose at Weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48	

End point values	RPV LA			
Subject group type	Subject analysis set			
Number of subjects analysed	278			
Units: Nanograms per milliliter				
geometric mean (confidence interval 95%)				
Pre-dose, Week 8, n=251	41.23 (38.74 to 43.88)			
Pre-dose, Week 12, n=236	46.86 (43.82 to 50.12)			
Pre-dose, Week 16, n=217	50.01 (47.06 to 53.15)			
Pre-dose, Week 20, n=233	52.76 (49.79 to 55.91)			
Pre-dose, Week 24, n=228	55.56 (52.48 to 58.82)			
Pre-dose, Week 28, n=220	59.46 (55.43 to 63.79)			
Pre-dose, Week 32, n=220	66.88 (62.95 to 71.05)			
Pre-dose, Week 36, n=215	69.09 (64.90 to 73.55)			
Pre-dose, Week 40, n=210	75.71 (71.38 to 80.29)			
Pre-dose, Week 44, n=216	77.96 (73.87 to 82.28)			
Pre-dose, Week 48, n=197	82.38 (77.82 to 87.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum concentration (Cmax) in plasma for CAB LA evaluable at Week 41

End point title	Maximum concentration (Cmax) in plasma for CAB LA evaluable at Week 41

End point description:

Blood samples will be collected at indicated time points for PK analysis of CAB LA. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Week 41- 1 Week post dose

End point values	CAB LA			
Subject group type	Subject analysis set			
Number of subjects analysed	236			
Units: Micrograms per milliliter				
geometric mean (confidence interval 95%)	4.0334 (3.8488 to 4.2269)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax in plasma for RPV LA evaluable at Week 41

End point title	Cmax in plasma for RPV LA evaluable at Week 41

End point description:

Blood samples will be collected at indicated time points for PK analysis of RPV LA. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Week 41- 1 Week post dose

End point values	RPV LA			
Subject group type	Subject analysis set			
Number of subjects analysed	236			
Units: Nanograms per milliliter				
geometric mean (confidence interval 95%)	106.3 (101.03 to 111.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with different demographic parameters for inter-subject variability

End point title	Number of participants with different demographic parameters for inter-subject variability

End point description:

Blood samples were planned to be collected at indicated time points for PK analysis of CAB LA and RPV LA. Demographic parameters including, but not limited to, age, sex, race, body weight, body mass index, and relevant laboratory parameters were planned to be evaluated as potential predictors of inter subject variability for pharmacokinetic parameters. This was an exploratory Outcome Measure. Data will not be analyzed and reported.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA	RPV LA		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[96]	0[97]		
Units: Participants				
number (not applicable)				

Notes:

[96] - PK Population

[97] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 5 in dimension scores using perception of injection questionnaire (PIN)-Last Observation Carried Forward (LOCF)

End point title	Change from Week 5 in dimension scores using perception of injection questionnaire (PIN)-Last Observation Carried Forward (LOCF)[98]

End point description:

PIN questionnaire explores bother of pain at injection site and injection site reactions (ISR),anxiety before and after injection, willingness to receive HIV injectable treatment and satisfaction with mode of treatment administration of individuals receiving injection and perceptions associated with receiving injections.This measure contains 21 items:pain at injection site, local site reactions, impact on functioning and willingness to pursue injectable treatment outside clinical trial. Scores range from 1 to 5; questions are phrased to ensure that 1:most favorable perception of vaccination, and 5:most unfavorable.Dimension scores include bother from ISR, leg movement, sleep and acceptability.Score of a domain is calculated as mean of all items with domain.Higher scores represent worse perception of injection.LOCF was primary method of analysis.Only those participants with data available at specified data points were analysed. p-value was derived only for acceptance: <0.001.

End point type	Secondary

End point timeframe:

Weeks 5 and at Weeks 41 and 48

Notes:

[98] - 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 specific to CAB LA + RPV LA (Q4W) arm

End point values	CAB LA + RPV LA (Q4W)			
Subject group type	Reporting group			
Number of subjects analysed	270[99]			
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Bother of ISRs, Week 41	-0.14 (± 0.551)			
Bother of ISRs, Week 48	-0.14 (± 0.639)			
Leg movement, Week 41	-0.58 (± 0.880)			
Leg movement, Week 48	-0.63 (± 0.964)			
Sleep, Week 41	-0.57 (± 0.925)			
Sleep, Week 48	-0.58 (± 1.033)			
Acceptance, Week 41	-0.36 (± 0.959)			
Acceptance, Week 48	-0.40 (± 0.943)			

Notes:

[99] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with extremely or very acceptable pain and local reaction: acceptability score on PIN questionnaire

End point title	Percentage of participants with extremely or very acceptable pain and local reaction: acceptability score on PIN questionnaire[100]

End point description:

PIN questionnaire explores bother of pain at injection site and injection site reactions (ISR),anxiety before and after injection, willingness to receive HIV injectable treatment, following visit and satisfaction with mode of treatment administration of individuals receiving injection and perceptions associated with receiving injections.This measure contains 21 items:pain at injection site, local site reactions, impact on functioning and willingness to pursue injectable treatment outside clinical trial. Scores range from 1 to 5; questions are phrased to ensure that 1:most favorable perception of vaccination, and 5:most unfavorable.Dimension scores include bother from ISR, leg movement, sleep and acceptability.Score of a domain is calculated as mean of all items with domain.Higher scores represent worse perception of injection.LOCF was primary method of analysis.Only those participants with data available at specified data points were analyzed (represented by n= X in category titles).

End point type	Secondary

End point timeframe:

Weeks 5, 41 and 48

Notes:

[100] - 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 specific to CAB LA + RPV LA (Q4W) arm

End point values	CAB LA + RPV LA (Q4W)			
Subject group type	Reporting group			
Number of subjects analysed	283[101]			
Units: Percentage of participants				
number (not applicable)				
Local reactions, Week 5, totally acceptable, n=270	47			
Local reactions,Week 5, very acceptable, n=270	29			
Local reactions, Week 5, moderate, n=270	16			
Local reactions, Week 5, little acceptable, n=270	6			
Local reactions, Week 5, not at all, n=270	3			
Pain, Week 5, totally acceptable, n=270	33			
Pain, Week 5, very acceptable, n=270	28			
Pain, Week 5, moderate acceptable, n=270	24			
Pain, Week 5, little acceptable, n=270	11			
Pain, Week 5, not at all acceptable, n=270	5			
Local reactions, week 41, totally, n=276	57			
Local reactions, Week 41, very acceptable, n=276	29			
Local reactions, Week 41, moderate, n=276	11			
Local reactions, Week 41, little acceptable, n=276	3			
Local reactions, Week 41, not at all, n=276	0.7			
Pain, Week 41, totally acceptable, n=276	45			
Pain, Week 41, very acceptable, n=276	35			
Pain, Week 41, moderate acceptable, n=276	14			
Pain, Week 41, little acceptable, n=276	4			
Pain, Week 41, not at all acceptable, n=276	1			
Local reactions, week 48, totally, n=278	55			
Local reactions, Week 48, very acceptable, n=278	31			
Local reactions, Week 48, moderate, n=278	11			
Local reactions, Week 48, little acceptable, n=278	2			
Local reactions, Week 48, not at all, n=278	0.7			
Pain, Week 48, totally acceptable, n=278	49			
Pain, Week 48, very acceptable, n=278	35			

Pain, Week 48, moderate acceptable, n=278	12			
Pain, Week 48 little acceptable, n=278	3			
Pain, Week 48, not at all acceptable, n=278	0.7			

Notes:

[101] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in life satisfaction (LISAT) using HIV/AIDs-targeted quality of life (HATQoL) questionnaire

End point title	Change from Baseline in life satisfaction (LISAT) using HIV/AIDs-targeted quality of life (HATQoL) questionnaire

End point description:

HATQoL comprises of three dimensions LISAT, medication worries (MEDWO) and disclosure worries (DISWO). For LISAT domain, each question is scored as 1-5, where 5 corresponds to satisfaction 'all of time' and 1 as 'none of time'. Total score for LISAT domain (sum of item scores for questions 1a to 1d) is transformed to a 0-100 scale using formula:[100/(20 minus 4)]*(raw total score for LISAT minus 4). Higher LISAT score, greater satisfaction to life. Transformed dimension score for each domain was summarized and analyzed. LOCF was primary method of analysis. Measure type was mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as last available value up to and including date of first Maintenance phase dose of IP. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only participants with data available at specified data points were analyzed (represented by n= X in category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and at Weeks 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[102]	283[103]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Week 24, n=252, 253	0.4 (-1.3 to 2.1)	-0.8 (-2.5 to 0.9)		
Week 48, n=253, 258	0.9 (-0.8 to 2.6)	0.0 (-1.6 to 1.7)		

Notes:

[102] - ITT-E Population

[103] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC

Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[104]
P-value	= 0.307
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	3.6

Notes:

[104] - Treatment comparison at Week 24 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Statistical analysis title	Statistical Analysis 2
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[105]
P-value	= 0.472
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	3.2

Notes:

[105] - Treatment comparison at Week 48 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Secondary: Change from Baseline in HIV medication, MEDWO using HATQoL

End point title	Change from Baseline in HIV medication, MEDWO using HATQoL

End point description:

HATQoL comprises of three dimensions: LISAT, MEDWO and DISWO. For the MEDWO domain, each question is scored as 1-5, where 5 is associated with medication worry ‘none of the time’ and 1 as ‘all of the time’. Total score for MEDWO domain (sum of item scores for questions 2a to 3e) is transformed to a 0-100 scale using formula: [100/(25 minus 5)]* (raw total score for MEDWO minus 5). Higher MEDWO scores correspond to lower medication worries. Transformed dimension score for each domain was summarized and analyzed. LOCF was used as primary method of analysis. Measure type was considered as mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as the last available value up to and including the date of first Maintenance phase dose of IP. Change from Baseline value is calculated as value at post-dose visit minus Baseline value.Only those participants with data available at specified data points were analyzed (represented by n= X in category titles).

End point type	Secondary

End point timeframe:

Baseline and at Weeks 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[106]	283[107]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Week 24, n=252, 253	3.2 (1.6 to 4.7)	1.4 (-0.1 to 3.0)		
Week 48, n=253, 258	1.4 (-0.3 to 3.1)	1.3 (-0.4 to 3.0)		

Notes:

[106] - ITT-E Population

[107] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[108]
P-value	= 0.116
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	3.9

Notes:

[108] - Treatment comparison at Week 24 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Statistical analysis title	Statistical Analysis 2
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[109]
P-value	= 0.944
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	2.5

Notes:

[109] - Treatment comparison at Week 48 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Secondary: Change from Baseline in DISWO using HATQoL

End point title	Change from Baseline in DISWO using HATQoL

End point description:

HATQoL comprises of three dimensions: LISAT, MEDWO and DISWO. For the DISWO domain, each question is scored as 1-5, where 5 is associated with disclosure worry 'none of the time' and 1 as 'all of the time'. Total score for DISWO domain (sum of item scores for questions 3a to 3e) is transformed to a 0-100 scale using formula: [100/(25 minus 5)]* (raw total score for DISWO minus 5). Higher DISWO total scores correspond to lower disclosure worries. Transformed dimension score for each domain was summarized and analyzed. LOCF was used as primary method of analysis. Measure type was considered as mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as last available value up to and including date of first Maintenance phase dose of IP. Change from Baseline value is calculated as value at post-dose visit minus Baseline value.Only those participants with data available at specified data points were analyzed (represented by n= X in category titles).

End point type	Secondary

End point timeframe:

Baseline and at Weeks 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[110]	283[111]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Week 24, n=252, 253	-0.8 (-3.9 to 2.3)	0.5 (-2.6 to 3.6)		
Week 48, n=253, 258	-3.6 (-6.6 to -0.6)	1.1 (-1.9 to 4.0)		

Notes:

[110] - ITT-E Population

[111] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[112]
P-value	= 0.552
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.7
upper limit	3

Notes:

[112] - Treatment comparison at Week 24 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Statistical analysis title	Statistical Analysis 2
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[113]
P-value	= 0.033
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	-4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.9
upper limit	-0.4

Notes:

[113] - Treatment comparison at Week 48 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Secondary: Change from Baseline in health status using 12-item short form survey (SF-12)

End point title	Change from Baseline in health status using 12-item short form survey (SF-12)

End point description:

The SF-12 questionnaire consists of 7 questions which measures degree of general health status and mental health distress. Each question is scored 0-5, except for question 2 scored 0-3. HRQoL using SF-12 for physical component summary (PCS) and mental component summary (MCS) were assessed for two treatment groups.Missing component scores was imputed using LOCF.PCS/MCS are calculated using computer software purchased from QualityMetric (http://www.qualitymetric.com).The higher the score, the better will be the health status.Measure type was considered as mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as the last available recorded value up to and including the date of first Maintenance phase dose of IP. Change from Baseline value is calculated as value at post-dose visit minus Baseline value.Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and at Weeks 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[114]	283[115]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
MCS, Week 24, n=251, 253	-0.045 (-0.963 to 0.874)	-1.066 (-1.980 to -0.151)		
MCS, Week 48, n=252, 258	-0.013 (-0.973 to 0.947)	-1.116 (-2.065 to -0.167)		

PCS, Week 24, n=251, 253	-0.019 (-0.568 to 0.531)	-0.201 (-0.748 to 0.347)		
PCS, Week 48, n=252, 258	-0.294 (-0.881 to 0.293)	-0.126 (-0.706 to 0.455)		

Notes:

[114] - ITT-E Population

[115] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[116]
P-value	= 0.122
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	1.021
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.275
upper limit	2.318

Notes:

[116] - Treatment comparison of SF-12 MCS at Week 24 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Statistical analysis title	Statistical Analysis 2
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[117]
P-value	= 0.109
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	1.103
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.248
upper limit	2.453

Notes:

[117] - Treatment comparison of SF-12 MCS at Week 48 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Statistical analysis title	Statistical Analysis 3
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC

Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[118]
P-value	= 0.645
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	0.182
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.594
upper limit	0.958

Notes:

[118] - Treatment comparison of SF-12 PCS at Week 24 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Statistical analysis title	Statistical Analysis 4
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[119]
P-value	= 0.689
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	-0.169
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.994
upper limit	0.657

Notes:

[119] - Treatment comparison of SF-12 PCS at Week 48 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Secondary: Change from Baseline in total treatment satisfaction using HIV treatment satisfaction questionnaire (HIVTSQs) at Weeks 4b, 24 and 44

End point title	Change from Baseline in total treatment satisfaction using HIV treatment satisfaction questionnaire (HIVTSQs) at Weeks 4b, 24 and 44

End point description:

HIVTSQs (status version) total treatment satisfaction score is computed with 1-11 items. Items 1-11 are summed to produce score with possible range of 0 to 66. Higher the score, greater improvement in satisfaction with treatment; lower score, greater the deterioration in satisfaction with treatment. A score of 0 represents no change. LOCF was primary method of analysis. Baseline value is defined as the last available value up to and including the date of first Maintenance phase dose of IP. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles). Adjusted mean and 95% CI of adjusted mean values has been presented.

End point type	Secondary

End point timeframe:

Baseline and at Weeks 4b, 24 and 44

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[120]	283[121]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Week 4b, n=257, 0	0.2 (-0.5 to 1.0)	99999 (99999 to 99999)		
Week 24, n=257, 253	1.6 (0.5 to 2.5)	-0.5 (-1.4 to 0.3)		
Week 44, n=257, 256	1.3 (0.5 to 2.1)	0.5 (-0.3 to 1.4)		

Notes:

[120] - ITT-E Population. 99999 indicates data not available due to insufficient participants

[121] - ITT-E Population. 99999 indicates data not available due to insufficient participants

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[122]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	3.4

Notes:

[122] - Treatment comparison at Week 24 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Statistical analysis title	Statistical Analysis 2
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[123]
P-value	= 0.217
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	1.9

Notes:

[123] - Treatment comparison at Week 44 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Secondary: Change in treatment satisfaction over time using HIVTSQc at Week 48

End point title	Change in treatment satisfaction over time using HIVTSQc at Week 48

End point description:

HIVTSQc (change version) total treatment satisfaction score is computed with 1-11 items. Items 1-11 are summed to produce score with possible range:-33 to 33. Higher scores represent greater improvement in treatment satisfaction compared to satisfaction with treatment received during the induction phase; lower scores representedeterioration in satisfaction with treatment. A score of 0 represents no change. LOCF was primary method of analysis. Baseline value is defined as the last available value up to and including the date of first Maintenance phase dose of IP. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	263[124]	266[125]		
Units: Scores on a scale				
arithmetic mean (standard error)	29.6 (± 0.49)	25.5 (± 0.48)		

Notes:

[124] - ITT-E Population.

[125] - ITT-E Population.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	529
Analysis specification	Pre-specified
Analysis type	other[126]
P-value	< 0.001
Method	ANOVA
Parameter estimate	Difference
Point estimate	4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.8
upper limit	5.5

Notes:

[126] - Treatment comparison of HIVTSQc-total treatment satisfaction score at Week 48 is presented, adjusted for Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Secondary: Change from Baseline in individual item scores of HIVTSQs at Weeks 4b, 24 and 44

End point title	Change from Baseline in individual item scores of HIVTSQs at Weeks 4b, 24 and 44

End point description:

HIVTSQs (status version) is a 12 item questionnaire. The individual item scores are ratedas 6 (very satisfied, convenient, flexible, etc.) to 0 (very dissatisfied, inconvenient, inflexible, etc.). Higher scores represent greater treatment satisfaction as compared to the past few weeks. LOCF was used as primary method of analysis. Baseline value is defined as the last available value up to and including the date of first Maintenance phase dose of IP. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and at Weeks 4b, 24 and 44

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[127]	283[128]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Item 1; Week 4b, n=257, 0	-0.0 (± 0.91)	99999 (± 99999)		
Item 1; Week 24, n=257, 255	0.1 (± 0.96)	-0.0 (± 0.95)		
Item 1; Week 44, n=257, 258	0.0 (± 1.02)	0.0 (± 0.93)		
Item 2; Week 4b, n=257, 0	0.0 (± 0.61)	99999 (± 99999)		
Item 2; Week 24, n=257, 255	-0.0 (± 0.62)	-0.0 (± 0.87)		
Item 2; Week 44, n=257, 258	-0.1 (± 0.61)	0.1 (± 0.62)		
Item 3; Week 4b, n=257, 0	0.2 (± 1.02)	99999 (± 99999)		
Item 3; Week 24, n=257, 255	-0.1 (± 1.21)	-0.0 (± 1.16)		
Item 3; Week 44, n=257, 258	-0.0 (± 1.35)	0.1 (± 1.22)		
Item 4; Week 4b, n=257, 0	0.1 (± 1.02)	99999 (± 99999)		
Item 4; Week 24, n=257, 255	0.1 (± 1.03)	-0.0 (± 1.14)		
Item 4; Week 44, n=257, 258	0.0 (± 1.08)	0.1 (± 1.10)		
Item 5; Week 4b, n=257, 0	0.1 (± 0.98)	99999 (± 99999)		
Item 5; Week 24, n=257, 255	0.4 (± 1.22)	-0.1 (± 1.05)		
Item 5; Week 44, n=257, 258	0.3 (± 1.28)	0.0 (± 1.06)		
Item 6; Week 4b, n=257, 0	0.1 (± 1.40)	99999 (± 99999)		
Item 6; Week 24, n=257, 255	0.3 (± 1.47)	-0.1 (± 1.63)		
Item 6; Week 44, n=257, 258	0.3 (± 1.70)	0.2 (± 1.48)		
Item 7; Week 4b, n=257, 0	0.0 (± 0.83)	99999 (± 99999)		
Item 7; Week 24, n=257, 255	0.0 (± 0.79)	0.0 (± 1.02)		

Item 7; Week 44, n=257, 258	0.1 (± 0.85)	0.1 (± 0.95)		
Item 8; Week 4b, n=257, 0	-0.0 (± 1.06)	99999 (± 99999)		
Item 8; Week 24, n=257, 255	0.2 (± 1.22)	-0.0 (± 1.11)		
Item 8; Week 44, n=257, 258	0.2 (± 1.27)	0.1 (± 1.16)		
Item 9; Week 4b, n=257, 0	-0.1 (± 0.85)	99999 (± 99999)		
Item 9; Week 24, n=257, 255	0.0 (± 0.78)	-0.1 (± 1.11)		
Item 9; Week 44, n=257, 258	0.0 (± 0.85)	0.0 (± 1.01)		
Item 10; Week 4b, n=257, 0	-0.1 (± 1.16)	99999 (± 99999)		
Item 10; Week 24, n=257, 256	0.4 (± 1.28)	-0.1 (± 1.35)		
Item 10; Week 44, n=257, 259	0.4 (± 1.33)	-0.0 (± 1.20)		
Item 11; Week 4b, n=257, 0	-0.0 (± 1.02)	99999 (± 99999)		
Item 11; Week 24, n=257, 255	0.2 (± 1.18)	-0.1 (± 0.99)		
Item 11; Week 44, n=257, 258	0.1 (± 1.18)	0.0 (± 0.97)		
Item 12; Week 4b, n=257, 0	-0.0 (± 0.99)	99999 (± 99999)		
Item 12; Week 24, n=257, 255	-0.4 (± 1.26)	0.1 (± 1.19)		
Item 12; Week 44, n=257, 258	-0.5 (± 1.20)	0.1 (± 1.29)		

Notes:

[127] - ITT-E Population. 99999 indicates data not available due to insufficient participants

[128] - ITT-E Population. 99999 indicates data not available due to insufficient participants

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in treatment acceptance at Weeks 8, 24 and 48 using "General acceptance" dimension of the Chronic Treatment Acceptance (ACCEPT) questionnaire

End point title	Change from Baseline in treatment acceptance at Weeks 8, 24 and 48 using "General acceptance" dimension of the Chronic Treatment Acceptance (ACCEPT) questionnaire

End point description:

ACCEPT questionnaire is generic medication acceptance measure assessing how participants weigh advantages and disadvantages of long-term medication. It consists 25 items, capturing six dimensions. 3 questions focusing on general acceptance of study medication were analyzed. Items scores are rated as 1-5 :1-totally disagree,2-somewhat disagree,3-somewhat agree,4-totally agree and 5-I don't know. Acceptance domain score (ranging from 0 to 100) is calculated using following formula:100*(mean of recoded items in dimension minus 1) divided by 2.LOCF was primary method of analysis. Measure type is mean for adjusted mean and dispersion measure: 95% CI. Baseline value is defined as the last available value up to and including the date of first Maintenance phase dose of IP. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at specified data points were analyzed (represented by n= X in category titles).

End point type	Secondary

End point timeframe:

Baseline and at Weeks 8, 24 and 48

End point values	CAB LA + RPV LA (Q4W)	ABC/ DTG/ 3TC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283[129]	283[130]		
Units: Scores on a scale				
arithmetic mean (confidence interval 95%)				
Week 8, n=253, 256	3.3 (0.8 to 5.8)	1.2 (-1.3 to 3.6)		
Week 24, 255, 261	3.7 (1.1 to 6.4)	1.1 (-1.5 to 3.7)		
Week 48, n=255, 262	3.0 (0.4 to 5.6)	0.8 (-1.7 to 3.4)		

Notes:

[129] - ITT-E Population

[130] - ITT-E Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[131]
P-value	= 0.232
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	5.7

Notes:

[131] - Treatment comparison at Week 8 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Statistical analysis title	Statistical Analysis 2
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[132]
P-value	= 0.154
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	6.4

Notes:

[132] - Treatment comparison Week 24 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Statistical analysis title	Statistical Analysis 3
Comparison groups	CAB LA + RPV LA (Q4W) v ABC/ DTG/ 3TC
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	other[133]
P-value	= 0.236
Method	ANCOVA
Parameter estimate	Adjusted difference
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	5.8

Notes:

[133] - Treatment comparison at Week 48 is presented, adjusted for Maintenance Baseline (Day 1) Score, Induction Baseline (Week -20) HIV-1 RNA (<100,000, >=100,000 c/mL), gender at birth, age (<50, >= 50 Years) and race (white, non-white).

Secondary: Change from 4b in tolerability of injection at Weeks 5, 40 and 41 using numeric rating scale (NRS) within CAB LA+RPV LA arm

End point title	Change from 4b in tolerability of injection at Weeks 5, 40 and 41 using numeric rating scale (NRS) within CAB LA+RPV LA arm[134]

End point description:

The NRS questionnaire is used to assess the tolerability of injections in CAB LA+RPV LA arm only. The questionnaire consists of one single question and will assess maximum level of pain experienced with the most recent injections ranking from no pain (0) to extreme pain (10). Missing scores was imputed using LOCF. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4b, 5, 40 and 41

Notes:

[134] - 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 specific to CAB LA + RPV LA (Q4W) arm

End point values	CAB LA + RPV LA (Q4W)			
Subject group type	Reporting group			
Number of subjects analysed	263[135]			
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 5	1.8 (± 2.78)			
Week 40	0.8 (± 2.72)			
Week 41	0.4 (± 2.69)			

Notes:

[135] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Non-serious AEs and SAEs were collected up to an average of 59 weeks	
Adverse event reporting additional description:	
AEs and SAEs were collected in Safety population.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	ABC/ DTG/ 3TC
Reporting group description:	
During Maintenance Phase (Day 1 to Week 100), participants continued to receive ABC/DTG/3TC. After completion of Maintenance Phase, participants who chose to enter the Extension Phase have the option to complete the study or switch to CAB LA+RPV LA	
Reporting group title	CAB LA+RPV LA (Q4W)
Reporting group description:	
Participants who received ABC/DTG/3TC for 20 Weeks (Week [-20] to Day 1) in the Induction Phase and who have an HIV-1 ribonucleic acid (RNA) <50 copies per millilter (c/mL) at Week (-4) entered Maintenance Phase (Day 1 to Week 100) to begin oral therapy with CAB 30 milligram (mg) + RPV 25 mg once daily for 4 Weeks. At Week 4b visit, participants received last dose of oral CAB + RPV and first dose CAB LA 600 mg + RPV LA 900 mg injections. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg at Week 8 and every four weeks (Q4W) through Week 100. After completion of Maintenance Phase, participants who chose to enter Extension Phase will continue to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up period.	

Serious adverse events	ABC/ DTG/ 3TC	CAB LA+RPV LA (Q4W)	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 283 (4.24%)	18 / 283 (6.36%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	1 / 283 (0.35%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Breast cancer			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kaposi's sarcoma			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Weight decreased			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Laceration			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Peripheral artery thrombosis			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			

subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Anal fistula			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal fissure			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Umbilical hernia			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Priapism			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocholecystis			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Drug abuse			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			

subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Hepatitis A			
subjects affected / exposed	1 / 283 (0.35%)	3 / 283 (1.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis pneumococcal			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	ABC/ DTG/ 3TC	CAB LA+RPV LA (Q4W)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	138 / 283 (48.76%)	252 / 283 (89.05%)	
Nervous system disorders			
Headache			
subjects affected / exposed	21 / 283 (7.42%)	39 / 283 (13.78%)	
occurrences (all)	24	48	
Dizziness			
subjects affected / exposed	3 / 283 (1.06%)	15 / 283 (5.30%)	
occurrences (all)	3	17	
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 283 (0.00%)	227 / 283 (80.21%)	
occurrences (all)	0	1879	
Injection site nodule			
subjects affected / exposed	0 / 283 (0.00%)	44 / 283 (15.55%)	
occurrences (all)	0	86	
Injection site induration			
subjects affected / exposed	0 / 283 (0.00%)	38 / 283 (13.43%)	
occurrences (all)	0	82	
Pyrexia			
subjects affected / exposed	4 / 283 (1.41%)	21 / 283 (7.42%)	
occurrences (all)	4	33	
Injection site swelling			
subjects affected / exposed	0 / 283 (0.00%)	23 / 283 (8.13%)	
occurrences (all)	0	38	
Injection site pruritus			
subjects affected / exposed	0 / 283 (0.00%)	16 / 283 (5.65%)	
occurrences (all)	0	25	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	25 / 283 (8.83%)	32 / 283 (11.31%)	
occurrences (all)	30	40	
Nausea			

subjects affected / exposed	11 / 283 (3.89%)	16 / 283 (5.65%)	
occurrences (all)	12	17	
Haemorrhoids			
subjects affected / exposed	3 / 283 (1.06%)	16 / 283 (5.65%)	
occurrences (all)	4	18	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	13 / 283 (4.59%)	22 / 283 (7.77%)	
occurrences (all)	14	26	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	48 / 283 (16.96%)	56 / 283 (19.79%)	
occurrences (all)	70	92	
Upper respiratory tract infection			
subjects affected / exposed	28 / 283 (9.89%)	38 / 283 (13.43%)	
occurrences (all)	35	50	
Influenza			
subjects affected / exposed	20 / 283 (7.07%)	25 / 283 (8.83%)	
occurrences (all)	22	27	
Gastroenteritis			
subjects affected / exposed	10 / 283 (3.53%)	15 / 283 (5.30%)	
occurrences (all)	10	18	
Pharyngitis			
subjects affected / exposed	9 / 283 (3.18%)	15 / 283 (5.30%)	
occurrences (all)	9	16	
Metabolism and nutrition disorders			
Vitamin D deficiency			
subjects affected / exposed	13 / 283 (4.59%)	23 / 283 (8.13%)	
occurrences (all)	13	23	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 December 2016	Amendment No.1: New Medical Monitor contact information; added lipid objective and endpoint to table in Synopsis; PRO assessments and timing clarification; provision of CAB+RPV LA until available in public/private sectors; allowed use of local labs for eligibility in exceptional circumstances; updated Time & Events Table; timing of ABC/DTG/3TC on the Day 1; continued use of contraception for at least 52 weeks after the last injection; revised text regarding provision of 'bridging' supply; CAB+RPV exposure may persist for more than 1 year after injections; edits to prohibited medication information; indicated drugs that cause TdP should be used with caution with RPV; background NRTI is not IP and accountability not required; film coat color for DTG changed from white to yellow; removed "protect from light" (for Triumeq and Tivicay); collection of device details for IM dosing in eCRF; additional information added regarding randomization schedule; added text stating investigator must discuss long-term study commitment with potential participants; added statement regarding serofast Screening RPR results; allowed serum pregnancy testing where required locally (e.g. when urine testing is not available); added option for PRO assessments to be collected on paper instrument if needed; removed information requiring collection of pregnancy information for female partners of male study participants; other minor corrections (e.g., typos, links, etc).
19 July 2017	Amendment No.2: Modified text to allow dose reduction for participants who have a decline in creatinine clearance to <50 mL/min during the Induction Phase; clarify that for participants not eligible to continue into the Maintenance Phase, only samples with HIV-1 RNA > 400 c/mL will be sent for resistance testing; add mitigation for electrocardiogram (ECG) pad removal; clarify +- 3 day window is for all oral dosing (both Induction and Maintenance Phase); add "LA Arm" back to columns for Week 68, 76, 84, 92 on Time and Events Schedule (hidden when column was narrowed); clarify Week 104b visit is specific to those participants transitioning from oral IP to CAB LA + RPV LA; clarification added to footnote 'p' that genetics sample can be collected at any visit after signing informed consent, but Week [-20] preferred; correct footnote on Week 5 visit to reflect footnote 't'; add footnote 'y' back to Time and Events column for Withdrawal Visit (for Induction Phase); add clarification to Time and Events column that Injection Site Reaction (ISR) assessments are only conducted for subjects receiving injections. Administrative typographical errors corrected (e.g. clarification provided regarding genetics sample taken after participants are enrolled into the study [vs when participants are randomized]), and investigator brochure (IB) references updated, references added.

25 June 2018	Amendment No.3: Changes for Amendment 3 were primarily 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 DTG at the time of conception. - A Risk Assessment table was added to include language regarding risk and mitigation of neural tube defects seen with DTG. - The withdrawal criteria were updated to include a reminder that females of reproductive potential who change their minds and desire to be pregnant should also be withdrawn from the study. - The Time and Events table was updated to include a reminder for investigators to check at every visit that females of reproductive potential are avoiding pregnancy. Additionally, clarifications were provided for the following: - the DTG IB should be referenced for additional risks, safety information, drug interactions, etc.; - 'suspected' was added to the text prior to the bulleted definition of suspected virologic failure; - specific storage conditions were removed from the protocol for IP, and a statement added to store according to product label; - insulin was removed from the section regarding clinical assessments performed during the study; - timeframe for pregnancy reporting and follow-up were updated to 24 hours to align with current reporting process; - prescribing information and IB references were updated.
24 September 2018	Amendment No.4: The primary reason for protocol amendment 04 was to allow an optional (vs mandatory) oral lead-in for participants randomized to the ABC/DTG/3TC arm who choose to continue into the Extension Phase of the study and receive CAB LA + RPV LA. The Appendix for contraceptive guidance and collection of pregnancy information was updated to be consistent with current protocol template text. Other minor clarifications were made as needed, e.g., the Columbia Suicide Severity Rating Scale (eCSSRs) timing in the footnote for the Time and Events Table, updated abbreviations, etc.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported