Clinical trial results:
A Phase IIIb, Randomized, Multicenter, Parallel-group, Non-inferiority, Open-label Study Evaluating the Efficacy, Safety, and Tolerability of Long-acting Cabotegravir Plus Long-acting Rilpivirine Administered Every 8 Weeks or Every 4 Weeks in HIV-1-infected Adults who are Virologically Suppressed

Summary

EudraCT number	2017-002946-62
Trial protocol	ES SE DE IT
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	11 June 2020
First version publication date	11 June 2020

Trial information

Trial identification

Sponsor protocol code	207966

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, TW8 9GS
Public contact	GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	17 September 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 June 2019
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 CAB LA + RPV LA every 8 weeks (every two months) compared to CAB LA + RPV LA every 4 weeks (monthly) over 48 weeks in suppressed HIV-1 infected antiretroviral therapy (ART)-experienced participants

Protection of trial subjects:

Participants entering the study from oral standard of care (SOC) received oral cabotegravir (CAB) 30 milligram (mg) + rilpivirine (RPV) 25 mg once daily during the 4-week oral lead-in phase to confirm tolerability prior to receiving CAB long acting (LA) + RPV LA injectable treatment.

In exceptional circumstances, to address pre-planned missed CAB LA + RPV LA dosing visits, in consultation with the medical monitor, Investigators may provide daily oral CAB 30 mg and RPV 25 mg as a short-term "bridging" strategy for participants who have begun CAB LA + RPV LA. In certain circumstances (e.g., prior to steady state dosing and following a >4 week oral bridge) repeating the loading doses of CAB intramuscular (IM) and RPV IM may be required. Should a participant require "oral bridging", sites must contact the study Medical Monitor for guidance with treatment and dosing strategies prior to a missed CAB LA + RPV LA dose.

All injections must be given intramuscularly in the gluteus medius. Sites may use their discretion as to where in the gluteus muscle each injection is given according to individual participant circumstance. If possible, injections should be spaced approximately 2 centimeter (cm) from one another, from the site of any previous injection or any injection site reaction.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 October 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 29
Country: Number of subjects enrolled	Australia: 23
Country: Number of subjects enrolled	Canada: 76
Country: Number of subjects enrolled	France: 55
Country: Number of subjects enrolled	Germany: 84
Country: Number of subjects enrolled	Italy: 49
Country: Number of subjects enrolled	Korea, Republic of: 27
Country: Number of subjects enrolled	Mexico: 16
Country: Number of subjects enrolled	Russian Federation: 138
Country: Number of subjects enrolled	South Africa: 82

Country: Number of subjects enrolled	Spain: 159
Country: Number of subjects enrolled	Sweden: 21
Country: Number of subjects enrolled	United States: 290
Worldwide total number of subjects	1049
EEA total number of subjects	368

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)	1021
From 65 to 84 years	28
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This non-inferiority study evaluated antiviral activity of cabotegravir(CAB) long acting(LA) 600 milligrams(mg) + rilpivirine(RPV) LA 900 mg administered every 8 weeks(Q8W) compared with CAB LA 400 mg+RPV LA 600 mg administered every 4 weeks(Q4W) over a 48-week period in virologically suppressed human immunodeficiency type 1 infection participants.

Pre-assignment

Screening details:

A total of 1049 eligible participants were randomized in a ratio of 1:1 to 1 of the 2 treatment arms in Maintenance Phase, of which 4 participants did not receive study treatment and 1045 participants were included in Intent to treat-Exposed Population. 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 Q8W

Arm description:

Eligible participants transitioning from antiretroviral (ART) standard of care (SOC) therapy arm in the ATLAS study (2016-001647-39) and randomized to receive CAB LA+RPV LA Q8W in the current study were administered oral therapy with CAB 30 mg + RPV 25 mg once daily at Day 1 for 4 weeks. Participants then received intramuscular (IM) injections of CAB LA 600 mg and RPV LA 900 mg at Week 4b and Week 8 followed by injections Q8W thereafter. Participants transitioned from the CAB LA+RPV LA Q4W arm of ATLAS study (2016-001647-39) received CAB LA 600 mg+RPV LA 900 mg intramuscular injections on Day 1, Week 8 and Q8W thereafter.

Arm type	Experimental
Investigational medicinal product name	CAB 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) IM injection at Week 4b after the last dose of CAB oral regimen. Participants then received CAB 2 mL injections Q8W from Week 8 to Week 48.

Investigational medicinal product name	RPV 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 IM injection at Week 4b after the last dose of RPV oral regimen. Participants then received RPV 2 mL injections Q8W from Week 8 to Week 48

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

Dosage and administration details:

Participants received both CAB 30 mg tablets once daily from Day 1 to Week 4b approximately the same time each day with a meal

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

Dosage and administration details:

Participants received both RPV 25 mg tablets once daily from Day 1 to Week 4b approximately the same time each day with a meal

Arm title	CAB LA + RPV LA Q4W

Arm description:

Eligible participants transitioning from ART SOC arm in the ATLAS study (2016-001647-39) and randomized to receive CAB LA+RPV LA Q4W in the current study were administered oral therapy with CAB 30 mg + RPV 25 mg once daily at Day 1 for 4 weeks. Participants then received a loading dose of CAB LA 600 mg and RPV LA 900 mg IM injections at Week 4b followed maintenance injections of CAB LA 400 mg +RPV LA 600 mg Q4W thereafter. Participants transitioned from the Q4W arm of ATLAS study (2016-001647-39) continued to receive CAB LA 400 mg+RPV LA 600 mg intramuscular injections administered Q4W from Day 1.

Arm type	Experimental
Investigational medicinal product name	CAB 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 mL IM injection at Week 4b after the last dose of CAB oral regimen. Participants then received CAB 2 mL injections Q4W from Week 8 to Week 48

Investigational medicinal product name	RPV 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 IM injection at Week 4b after the last dose of RPV oral regimen. Participants then received RPV 2 mL injections Q4W from Week 8 to Week 48

Number of subjects in period 1[1]	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W
Started	522	523
Completed	0	0
Not completed	522	523
Consent withdrawn by subject	6	21
Physician decision	5	1
On-going	486	481
Adverse event, non-fatal	12	13
Pregnancy	1	3
Lost to follow-up	2	-

Protocol deviation	1	1
Lack of efficacy	9	3

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: A total 1049 participants were enrolled in the study out of which 4 participants did not receive the study treatment.

Baseline characteristics

Reporting groups

Reporting group title	CAB LA + RPV LA Q8W

Reporting group description:

Eligible participants transitioning from antiretroviral (ART) standard of care (SOC) therapy arm in the ATLAS study (2016-001647-39) and randomized to receive CAB LA+RPV LA Q8W in the current study were administered oral therapy with CAB 30 mg + RPV 25 mg once daily at Day 1 for 4 weeks. Participants then received intramuscular (IM) injections of CAB LA 600 mg and RPV LA 900 mg at Week 4b and Week 8 followed by injections Q8W thereafter. Participants transitioned from the CAB LA+RPV LA Q4W arm of ATLAS study (2016-001647-39) received CAB LA 600 mg+RPV LA 900 mg intramuscular injections on Day 1, Week 8 and Q8W thereafter.

Reporting group title	CAB LA + RPV LA Q4W

Reporting group description:

Eligible participants transitioning from ART SOC arm in the ATLAS study (2016-001647-39) and randomized to receive CAB LA+RPV LA Q4W in the current study were administered oral therapy with CAB 30 mg + RPV 25 mg once daily at Day 1 for 4 weeks. Participants then received a loading dose of CAB LA 600 mg and RPV LA 900 mg IM injections at Week 4b followed maintenance injections of CAB LA 400 mg +RPV LA 600 mg Q4W thereafter. Participants transitioned from the Q4W arm of ATLAS study (2016-001647-39) continued to receive CAB LA 400 mg+RPV LA 600 mg intramuscular injections administered Q4W from Day 1.

Reporting group values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W	Total
Number of subjects	522	523	1045
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)	502	515	1017
From 65-84 years	20	8	28
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	42.7	42.3	
standard deviation	± 11.16	± 10.58	-
Sex/Gender, Customized Units: Participants			
Reported gender=Female	142	146	288
Reported gender=Male	380	377	757
Race/Ethnicity, Customized Units: Subjects			
American Indian (AI) or Alaska Native (AN)	17	11	28
Asian-Central/South Asian Heritage (H)	1	1	2
Asian-East Asian H	20	12	32
Asian-Japanese H	0	2	2

Asian-South East Asian (SEA) H	8	7	15
Black or African American (AA)	101	90	191
Native Hawaiian (NH) or other Pacific Islander	3	1	4
White-Arabic/North African H	2	4	6
White-White/Caucasian/European (EU) H	368	388	756
White-Mixed White Race	0	1	1
Multiple-AI/AN and Black/AA/White/Caucasian/EU H	1	1	2
Multiple-AI/AN and NH/Other Pacific Islander	1	0	1
Multiple-SEA H and White/Caucasian/ EU H	0	1	1
Multiple-Black/AA and White-Arabic/North African H	0	1	1
Multiple-Black/AA and White/Caucasian/EU H	0	3	3
Sex/Gender, Customized Units: Subjects			
Sex at Birth, Female	137	143	280
Sex at Birth, Male	385	380	765

End points

End points reporting groups

Reporting group title	CAB LA + RPV LA Q8W

Reporting group description:

Eligible participants transitioning from antiretroviral (ART) standard of care (SOC) therapy arm in the ATLAS study (2016-001647-39) and randomized to receive CAB LA+RPV LA Q8W in the current study were administered oral therapy with CAB 30 mg + RPV 25 mg once daily at Day 1 for 4 weeks. Participants then received intramuscular (IM) injections of CAB LA 600 mg and RPV LA 900 mg at Week 4b and Week 8 followed by injections Q8W thereafter. Participants transitioned from the CAB LA+RPV LA Q4W arm of ATLAS study (2016-001647-39) received CAB LA 600 mg+RPV LA 900 mg intramuscular injections on Day 1, Week 8 and Q8W thereafter.

Reporting group title	CAB LA + RPV LA Q4W

Reporting group description:

Eligible participants transitioning from ART SOC arm in the ATLAS study (2016-001647-39) and randomized to receive CAB LA+RPV LA Q4W in the current study were administered oral therapy with CAB 30 mg + RPV 25 mg once daily at Day 1 for 4 weeks. Participants then received a loading dose of CAB LA 600 mg and RPV LA 900 mg IM injections at Week 4b followed maintenance injections of CAB LA 400 mg +RPV LA 600 mg Q4W thereafter. Participants transitioned from the Q4W arm of ATLAS study (2016-001647-39) continued to receive CAB LA 400 mg+RPV LA 600 mg intramuscular injections administered Q4W from Day 1.

Subject analysis set title	CAB LA Q8W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received 2 x 3ml CAB LA injections at week 4b and 2 x 3 ml CAB LA injections Q8W thereafter

Subject analysis set title	CAB LA Q4W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received 2 x 3ml CAB LA injections at week 4b and 2 x 2 ml CAB LA injections Q4W thereafter

Subject analysis set title	RPV LA Q8W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received 2 x 3ml RPV LA injections at week 4b and 2 x 3 ml RPV LA injections Q8W thereafter

Subject analysis set title	RPV LA Q4W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received 2 x 3ml RPV LA injections at week 4b and 2 x 2 ml RPV LA injections Q4W thereafter

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

Subject analysis set description:

Participants in this arm received CAB LA 600 mg Q8W and 400 mg Q4W at week 4b, week 8 and then 8 weekly thereafter

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

Subject analysis set description:

Participants in this arm received RPV LA 900 mg Q8W and 600 mg Q4W at week 4b, week 8 and then 8 weekly thereafter

Subject analysis set title	CAB LA Q8W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received 2 x 3 ml CAB LA injections at week 4b and 2 x 3 ml CAB La injections Q8W therafter

Subject analysis set title	CAB LA Q4W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received 2 x 3 ml CAB LA injections at week 4b and 2 x 2 ml CAB LA injections Q4W thereafter

Subject analysis set title	RPV LA Q8W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received 2 x 3 ml RPV LA injections at week 4b and 2 x 3 ml RPV LA injections Q8W thereafter

Subject analysis set title	RPV LA Q4W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received 2 x 3ml RPV LA injections at week 4b and 2 x 2 ml RPV LA injections Q4W thereafter

Primary: Percentage of participants with plasma human immunodeficiency virus-ribonucleic acid (HIV-RNA) >=50 copies per milliliter (c/mL) as per Food and Drug Administration (FDA) Snapshot algorithm at Week 48

End point title	Percentage of participants with plasma human immunodeficiency virus-ribonucleic acid (HIV-RNA) >=50 copies per milliliter (c/mL) as per Food and Drug Administration (FDA) Snapshot algorithm at Week 48

End point description:

Percentage of participants with HIV-1 RNA >=50 c/mL as per FDA snapshot algorithm at Week 48 was assessed to demonstrate the non-inferior antiviral activity of CAB LA+RPV LA Q8W compared to CAB LA + RPV LA Q4W regimen over 48 weeks in HIV-1 infected ART experienced participants. The HIV-1 RNA >=50 c/mL per Snapshot algorithm was determined by the last on-treatment HIV-1 RNA measurement within the Week 48 analysis visit window. Intent-to-treat-Exposed (ITT-E) Population comprised of all randomized participants who received at least one dose of study treatment. Participants were assessed according to their randomized treatment, regardless of the treatment they received.

End point type	Primary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[1]	523[2]		
Units: Percentage of participants				
number (not applicable)	1.7	1.0		

Notes:

[1] - ITT-E Population.

[2] - ITT-E Population.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted CMH estimate of the difference in the percentage of participants with Plasma HIV-1 >=50 c/mL between each treatment group (Q8W minus Q4W) and corresponding 95% confidence interval is presented.

Comparison groups	CAB LA + RPV LA Q8W v CAB LA + RPV LA Q4W

Number of subjects included in analysis	1045
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Adjusted difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	2.2

Notes:

[3] - Non-inferiority was concluded if the upper bound of the two-sided 95% confidence interval (CI) for the Cochran-Mantel Haenzel (CMH) adjusted treatment difference (Q8W minus Q4W) is less than 4%.

Secondary: Percentage of participants with plasma HIV-1 RNA <50 c/mL using FDA Snapshot algorithm at Week 48

End point title	Percentage of participants with plasma HIV-1 RNA <50 c/mL using FDA Snapshot algorithm at Week 48

End point description:

Percentage of participants with plasma HIV-1 RNA <50 c/mL at Week 48 using FDA Snapshot algorithm was assessed to demonstrate antiviral activity of CAB LA+RPV LA Q8W compared to CAB LA+ RPV LA Q4W. The HIV-1 RNA <50 c/mL per Snapshot algorithm was determined by last on-treatment HIV-1 RNA measurement within the analysis visit window. The 95% CIs were derived using normal approximation (Wald CI)

End point type	Secondary

End point timeframe:

Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[4]	523[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:

Adjusted CMH estimate of the difference in the percentage of participants with Plasma HIV-1 <50 c/mL between each treatment group (Q8W-Q4W) and corresponding 95% CI is presented.

Comparison groups	CAB LA + RPV LA Q8W v CAB LA + RPV LA Q4W
Number of subjects included in analysis	1045
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Adjusted difference
Point estimate	0.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	3.7

Notes:

[6] - Non-inferiority was concluded if the upper bound of the two-sided 95% CI for the CMH adjusted treatment difference (Q8W minus Q4W) is greater than -10%

Secondary: Percentage of participants with plasma HIV-1 RNA <50 c/mL using FDA Snapshot algorithm at Week 24

End point title	Percentage of participants with plasma HIV-1 RNA <50 c/mL using FDA Snapshot algorithm at Week 24

End point description:

Percentage of participants with plasma HIV-1 RNA <50 c/mL at Week 48 using FDA Snapshot algorithm was assessed to demonstrate antiviral activity of CAB LA+RPV LA Q8W compared to CAB LA+ RPV LA Q4W. The HIV-1 RNA <50 c/mL per Snapshot algorithm was determined by last on-treatment HIV-1 RNA measurement within the analysis visit window. The 95% CIs were derived using normal approximation (Wald CI)

End point type	Secondary

End point timeframe:

Week 24

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[7]	523[8]		
Units: Percentage of participants				
number (confidence interval 95%)	95 (93 to 97)	95 (94 to 97)		

Notes:

[7] - ITT-E Population.

[8] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with protocol defined confirmed virologic failure (CVF) through Weeks 24 and 48

End point title	Percentage of participants with protocol defined confirmed virologic failure (CVF) through Weeks 24 and 48

End point description:

CVF was defined as rebound as indicated by two consecutive plasma HIV-1-RNA levels >=200 c/mL after prior suppression to <200 c/mL. Cumulative percentage of participants with protocol defined CVF up to Weeks 24 and 48 has been presented.

End point type	Secondary

End point timeframe:

Weeks 24 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[9]	523[10]		
Units: Percentage of participants				
number (not applicable)				
Week 24	1.3	0.2		
Week 48	1.5	0.4		

Notes:

[9] - ITT-E Population.

[10] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with HIV-RNA >=50 c/mL as per FDA Snapshot algorithm at Week 24

End point title	Percentage of participants with HIV-RNA >=50 c/mL as per FDA Snapshot algorithm at Week 24

End point description:

Percentage of participants with plasma HIV-1 RNA >=50 c/mL at Week 24 using FDA Snapshot algorithm was assessed to demonstrate antiviral activity of CAB LA+RPV LA Q8W compared to CAB LA+ RPV LA Q4W. The HIV-1 RNA >=50 c/mL per Snapshot algorithm was determined by the last on-treatment HIV-1 RNA measurement within the analysis visit window. The 95% CIs were derived using normal approximation (Wald CI).

End point type	Secondary

End point timeframe:

Weeks 24

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[11]	523[12]		
Units: Percentage of participants				
number (confidence interval 95%)	2.1 (0.9 to 3.3)	1.5 (0.5 to 2.6)		

Notes:

[11] - ITT-E Population.

[12] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Plasma samples were collected for quantitative analysis of HIV-1 RNA. 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:

Weeks 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	493[13]	487[14]		
Units: Log 10 c/mL				
arithmetic mean (standard deviation)	1.599 (± 0.0870)	1.593 (± 0.0302)		

Notes:

[13] - ITT-E Population.

[14] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Plasma samples were collected for quantitative analysis of HIV-1 RNA. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. Change from Baseline is defined as post-dose visit value minus Baseline value. Logarithm to base 10 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:

Baseline (Day 1) and Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	493[15]	487[16]		
Units: Log 10 c/mL				
arithmetic mean (standard deviation)	0.007 (± 0.0888)	-0.015 (± 0.1673)		

Notes:

[15] - ITT-E Population.

[16] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for cluster of differentiation 4 plus (CD4+) at Week 48

End point title	Absolute values for cluster of differentiation 4 plus (CD4+) at Week 48

End point description:

Blood samples were collected and CD4+ cell count assessment by flow cytometry was carried out to evaluate the immunologic activity of CAB LA+RPV LA Q8W compared to CAB LA+RPV LA Q8W. 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 Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	493[17]	486[18]		
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)	685.9 (± 261.70)	700.0 (± 278.18)		

Notes:

[17] - ITT-E Population.

[18] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Blood samples were collected and CD4+ cell count assessment by flow cytometry was carried out to evaluate the immunologic activity of CAB LA+RPV LA Q8W compared to CAB LA+RPV LA Q4W. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. Change from Baseline is defined as post-dose visit value minus 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 Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	493[19]	486[20]		
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)	5.3 (± 168.62)	-24.6 (± 199.02)		

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 >=5% incidence) and serious adverse events (SAEs)-Maintenance phase

End point title	Number of participants with non-serious adverse events (non-SAEs >=5% incidence) and serious adverse events (SAEs)-Maintenance phase

End point description:

An adverse event 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. A SAE is defined as 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 judgement. Safety Population comprised of all randomized participants who received at least one dose of study treatment. Participants were assessed according to actual treatment received.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[21]	523[22]		
Units: Participants				
Any non-SAE (>=5%)	429	427		
Any SAE	27	19		

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-Maintenance phase

End point title	Number of participants with severity of adverse events-Maintenance phase

End point description:

Severity of adverse events were defined as per The Division of Acquired Immunodeficiency Syndrome (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS adverse events Grading Table). Severity grades for adverse events were as Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (Potentially life-threatening) and Grade 5 (all deaths related to an AE).

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[23]	523[24]		
Units: Participants				
Grade 1	201	195		
Grade 2	231	238		
Grade 3	38	43		
Grade 4	2	6		
Grade 5	1	0		

Notes:

[23] - Safety Population.

[24] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with maximum Post-Baseline chemistry toxicities-Maintenance phase

End point title	Number of participants with maximum Post-Baseline chemistry toxicities-Maintenance phase

End point description:

Clinical chemistry toxicities were graded as per the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table)Blood samples were collected for the analysis of following clinical chemistry parameters: alanine aminotransferase (ALT), albumin, alkaline phosphate (ALP), aspartate aminotranferase (AST), bilirubin, carbon dioxide (CO2), cholesterol, creatinine kinase, creatinine, glomerular filtration rate (GFR) from creatinine adjusted for bovine serum albumin (BSA), glucose, hyperglycemia, hyperkalemia, hypernatremia, hypoglycemia, hypokalemia, hyponatremia, low density lipoprotein (LDL) calculation, lipase, phosphate, potassium, sodium and triglycerides. Severity grades were: Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe) and Grade 4 (Potentially life-threatening).

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[25]	523[26]		
Units: Participants				
ALT, Grade 1	45	49		
ALT, Grade 2	10	13		
ALT, Grade 3	1	3		
ALT, Grade 4	1	2		
Albumin, Grade 1	1	0		
Albumin, Grade 2	1	1		
Albumin, Grade 3	0	0		
Albumin, Grade 4	0	0		
ALP, Grade 1	1	5		
ALP, Grade 2	0	0		
ALP, Grade 3	0	0		

ALP, Grade 4	0	0		
AST, Grade 1	32	44		
AST, Grade 2	10	13		
AST, Grade 3	2	4		
AST, Grade 4	1	2		
Bilirubin, Grade 1	27	25		
Bilirubin, Grade 2	7	5		
Bilirubin, Grade 3	1	1		
Bilirubin, Grade 4	1	1		
CO2, Grade 1	98	111		
CO2, Grade 2	2	1		
CO2, Grade 3	0	0		
CO2, Grade 4	0	0		
Cholesterol, Grade 1	50	52		
Cholesterol, Grade 2	31	30		
Cholesterol, Grade 3	2	3		
Cholesterol, Grade 4	0	0		
Creatinine Kinase, Grade 1	41	32		
Creatinine Kinase, Grade 2	22	19		
Creatinine Kinase, Grade 3	7	9		
Creatinine Kinase, Grade 4	9	14		
Creatinine, Grade 1	5	9		
Creatinine, Grade 2	2	1		
Creatinine, Grade 3	0	0		
Creatinine, Grade 4	0	0		
GFR from creatinine adjusted for BSA, Grade 1	0	0		
GFR from creatinine adjusted for BSA, Grade 2	110	134		
GFR from creatinine adjusted for BSA, Grade 3	15	19		
GFR from creatinine adjusted for BSA, Grade 4	0	1		
Glucose, Grade 1	84	87		
Glucose, Grade 2	34	43		
Glucose, Grade 3	3	5		
Glucose, Grade 4	1	1		
Hyperglycemia, Grade 1	80	77		
Hyperglycemia, Grade 2	32	38		
Hyperglycemia, Grade 3	2	5		
Hyperglycemia, Grade 4	0	0		
Hyperkalemia, Grade 1	8	2		
Hyperkalemia, Grade 2	0	1		
Hyperkalemia, Grade 3	0	0		
Hyperkalemia, Grade 4	0	1		
Hypernatremia, Grade 1	6	2		
Hypernatremia, Grade 2	0	0		
Hypernatremia, Grade 3	0	0		
Hypernatremia, Grade 4	0	0		
Hypoglycemia, Grade 1	11	13		
Hypoglycemia, Grade 2	2	5		
Hypoglycemia, Grade 3	1	0		
Hypoglycemia, Grade 4	1	1		

Hypokalemia, Grade 1	10	8		
Hypokalemia, Grade 2	0	0		
Hypokalemia, Grade 3	0	0		
Hypokalemia, Grade 4	0	0		
Hyponatremia, Grade 1	23	26		
Hyponatremia, Grade 2	0	1		
Hyponatremia, Grade 3	0	0		
Hyponatremia, Grade 4	0	0		
LDL Cholesterol calculation, Grade 1	40	41		
LDL Cholesterol calculation, Grade 2	20	26		
LDL Cholesterol calculation, Grade 3	9	4		
LDL Cholesterol calculation, Grade 4	0	0		
Lipase, Grade 1	40	44		
Lipase, Grade 2	31	44		
Lipase, Grade 3	13	4		
Lipase, Grade 4	3	6		
Phosphate, Grade 1	75	75		
Phosphate, Grade 2	20	17		
Phosphate, Grade 3	0	2		
Phosphate, Grade 4	0	0		
Potassium, Grade 1	18	10		
Potassium, Grade 2	0	1		
Potassium, Grade 3	0	0		
Potassium, Grade 4	0	1		
Sodium, Grade 1	29	28		
Sodium, Grade 2	0	1		
Sodium, Grade 3	0	0		
Sodium, Grade 4	0	0		
Triglycerides, Grade 1	51	42		
Triglycerides, Grade 2	11	3		
Triglycerides, Grade 3	4	2		
Triglycerides, Grade 4	0	2		

Notes:

[25] - Safety Population.

[26] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with maximum Post-Baseline hematology toxicities-Maintenance phase

End point title	Number of participants with maximum Post-Baseline hematology toxicities-Maintenance phase

End point description:

The hematology toxicities were graded as per the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table). Blood samples were collected for the analysis of following hematology parameters: hemoglobin, leukocytes, neutrophils and platelets. Severity grades were as Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe) and Grade 4 (Potentially life-threatening).

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[27]	523[28]		
Units: Participants				
Hemoglobin, Grade 1	9	4		
Hemoglobin, Grade 2	1	3		
Hemoglobin, Grade 3	2	4		
Hemoglobin, Grade 4	0	0		
Leukocytes, Grade 1	12	5		
Leukocytes, Grade 2	0	0		
Leukocytes, Grade 3	1	0		
Leukocytes, Grade 4	0	0		
Neutrophils, Grade 1	7	6		
Neutrophils, Grade 2	8	5		
Neutrophils, Grade 3	1	2		
Neutrophils, Grade 4	2	1		
Platelets, Grade 1	8	8		
Platelets, Grade 2	1	1		
Platelets, Grade 3	1	1		
Platelets, Grade 4	0	0		

Notes:

[27] - Safety Population.

[28] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who discontinued treatment due to adverse events-Maintenance phase

End point title	Percentage of participants who discontinued treatment due to adverse events-Maintenance phase

End point description:

An adverse event 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. Percentage of participants with adverse events leading to withdrawal has been presented.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[29]	523[30]		
Units: Percentage of participants	2	2		

Notes:

[29] - Safety Population.

[30] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: ALT, ALP, AST and creatinine kinase over time

End point title	Change from Baseline in clinical chemistry parameters: ALT, ALP, AST and creatinine kinase over time

End point description:

Blood samples were collected for the analysis of clinical chemical parameters including ALT, ALP, AST and creatinine kinase. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[31]	523[32]		
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT, Week 4, n=326, 520	-1.3 (± 11.11)	0.1 (± 14.01)		
ALT, Week 8, n=510, 515	0.8 (± 21.28)	0.3 (± 15.65)		
ALT, Week 16, n=515, 513	1.5 (± 47.60)	-0.7 (± 12.29)		
ALT, Week 24, n=505, 503	1.9 (± 63.03)	-0.3 (± 13.39)		
ALT, Week 32, n=499, 498	-0.4 (± 12.60)	2.4 (± 33.72)		
ALT, Week 40, n=495, 490	0.4 (± 13.50)	6.6 (± 112.13)		
ALT, Week 48, n=493, 486	1.1 (± 16.39)	1.6 (± 18.61)		
ALP, Week 4, n=326, 520	-5.5 (± 12.09)	-2.1 (± 10.25)		
ALP, Week 8, n=510, 515	-4.1 (± 13.07)	-3.3 (± 11.31)		
ALP, Week 16, n=515, 513	-4.8 (± 14.65)	-4.2 (± 13.07)		
ALP, Week 24, n=505, 503	-5.2 (± 16.04)	-4.0 (± 13.42)		
ALP, Week 32, n=499, 498	-5.7 (± 17.14)	-4.1 (± 14.95)		
ALP, Week 40, n=495, 490	-5.9 (± 17.61)	-3.9 (± 16.09)		
ALP, Week 48, n=493, 486	-6.6 (± 17.18)	-4.5 (± 15.02)		
AST, Week 4, n=326, 520	-0.6 (± 13.25)	-0.3 (± 18.47)		
AST, Week 8, n=510, 515	0.6 (± 11.71)	0.0 (± 14.46)		
AST, Week 16, n=515, 513	1.2 (± 24.79)	-0.3 (± 16.58)		
AST, Week 24, n=505, 503	1.6 (± 53.81)	-0.2 (± 21.65)		

AST, Week 32, n=499, 498	-1.6 (± 8.84)	0.8 (± 34.81)		
AST, Week 40, n=495, 490	-1.0 (± 10.14)	2.5 (± 66.54)		
AST, Week 48, n=493, 486	-0.2 (± 12.48)	-0.7 (± 16.12)		
Creatinine kinase, Week 4, n=326, 520	30.2 (± 689.41)	-29.3 (± 717.51)		
Creatinine kinase, Week 8, n=510, 515	24.1 (± 479.84)	-23.7 (± 682.90)		
Creatinine kinase, Week 16, n=515, 513	30.6 (± 692.65)	-4.7 (± 856.65)		
Creatinine kinase, Week 24, n=505, 503	-13.6 (± 265.16)	31.1 (± 1198.22)		
Creatinine kinase, Week 32, n=499, 498	-23.3 (± 314.46)	-5.8 (± 787.02)		
Creatinine kinase, Week 40, n=495, 490	-12.5 (± 336.08)	34.2 (± 1288.66)		
Creatinine kinase, Week 48, n=493, 486	17.9 (± 411.70)	-2.9 (± 810.46)		

Notes:

[31] - Safety Population.

[32] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameter: albumin over time

End point title	Change from Baseline in clinical chemistry parameter: albumin over time

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: albumin. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[33]	523[34]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Week 4, n=326, 520	-0.5 (± 2.32)	-0.2 (± 2.45)		
Week 8, n=510, 515	-0.3 (± 2.48)	-0.1 (± 2.48)		
Week 16, n=515, 513	-0.3 (± 2.56)	-0.4 (± 2.51)		
Week 24, n=505, 503	-0.0 (± 2.49)	-0.2 (± 2.59)		
Week 32, n=499, 498	-0.2 (± 2.63)	-0.3 (± 2.68)		
Week 40, n=495, 490	0.1 (± 2.68)	-0.3 (± 2.54)		
Week 48, n=493, 486	-0.2 (± 2.59)	-0.2 (± 2.60)		

Notes:

[33] - Safety Population.

[34] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: bilirubin and creatinine over time

End point title	Change from Baseline in clinical chemistry parameters: bilirubin and creatinine over time

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: bilirubin and creatinine. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[35]	523[36]		
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin, Week 4, n=326, 520	0.4 (± 6.44)	0.1 (± 5.70)		
Bilirubin, Week 8, n=510, 515	0.4 (± 5.68)	0.1 (± 5.39)		
Bilirubin, Week 16, n=515, 513	0.5 (± 5.78)	0.2 (± 5.69)		
Bilirubin, Week 24, n=505, 503	0.8 (± 9.42)	0.5 (± 5.23)		
Bilirubin, Week 32, n=499, 498	0.5 (± 5.54)	0.4 (± 5.46)		
Bilirubin, Week 40, n=495, 490	0.7 (± 6.00)	0.4 (± 5.77)		
Bilirubin, Week 48, n=493, 486	0.4 (± 5.77)	0.7 (± 4.93)		
Creatinine, Week 4, n=326, 521	0.89 (± 8.768)	-0.36 (± 7.215)		
Creatinine, Week 8, n=510, 515	-0.94 (± 8.638)	-0.39 (± 8.191)		
Creatinine, Week 16, n=515, 513	-0.24 (± 8.973)	-0.03 (± 8.516)		
Creatinine, Week 24, n=505, 503	0.22 (± 9.085)	0.94 (± 9.591)		
Creatinine, Week 32, n=499, 498	1.01 (± 9.490)	2.09 (± 9.313)		
Creatinine, Week 40, n=495, 490	1.02 (± 9.604)	2.05 (± 9.414)		
Creatinine, Week 48, n=493, 486	1.30 (± 9.813)	2.30 (± 8.678)		

Notes:

[35] - Safety Population.

[36] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: CO2, chloride, phosphate, potassium, sodium and urea over time

End point title	Change from Baseline in clinical chemistry parameters: CO2, chloride, phosphate, potassium, sodium and urea over time

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: CO2, chloride, phosphate, potassium, sodium and urea. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[37]	523[38]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
CO2, Week 4, n=326, 520	-0.5 (± 2.29)	-0.7 (± 2.32)		
CO2, Week 8, n=510, 515	-0.8 (± 2.12)	-0.8 (± 2.23)		
CO2, Week 16, n=515, 513	-1.0 (± 2.31)	-0.9 (± 2.33)		
CO2, Week 24, n=505, 503	-0.7 (± 2.38)	-0.7 (± 2.28)		
CO2, Week 32, n=499, 498	-0.9 (± 2.31)	-0.8 (± 2.43)		
CO2, Week 40, n=495, 490	-0.6 (± 2.33)	-0.7 (± 2.44)		
CO2, Week 48, n=493, 485	-0.4 (± 2.32)	-0.4 (± 2.41)		
Chloride, Week 4, n=326, 520	0.6 (± 2.19)	0.2 (± 2.35)		
Chloride, Week 8, n=510, 515	0.3 (± 2.24)	0.2 (± 2.34)		
Chloride, Week 16, n=515, 513	0.4 (± 2.30)	0.2 (± 2.40)		
Chloride, Week 24, n=505, 503	0.1 (± 2.36)	-0.1 (± 2.59)		
Chloride, Week 32, n=499, 498	0.2 (± 2.34)	0.1 (± 2.64)		
Chloride, Week 40, n=495, 490	-0.1 (± 2.46)	0.0 (± 2.36)		
Chloride, Week 48, n=493, 486	-0.0 (± 2.25)	-0.1 (± 2.46)		
Phosphate, Week 4, n=326, 520	0.054 (± 0.182)	0.018 (± 0.167)		
Phosphate, Week 8, n=510, 515	0.025 (± 0.177)	0.029 (± 0.160)		
Phosphate, Week 16, n=515, 513	0.017 (± 0.181)	0.007 (± 0.172)		
Phosphate, Week 24, n=505, 502	0.016 (± 0.170)	-0.004 (± 0.168)		
Phosphate, Week 32, n=499, 498	-0.001 (± 0.183)	0.001 (± 0.172)		
Phosphate, Week 40, n=495, 490	0.014 (± 0.180)	0.001 (± 0.170)		
Phosphate, Week 48, n=493, 486	0.007 (± 0.169)	0.010 (± 0.157)		
Potassium, Week 4, n=326, 520	0.03 (± 0.337)	0.03 (± 0.303)		

Potassium, Week 8, n=510, 515	0.04 (± 0.317)	0.04 (± 0.331)		
Potassium, Week 16, n=515, 513	0.03 (± 0.328)	0.03 (± 0.341)		
Potassium, Week 24, n=505, 503	0.04 (± 0.338)	0.03 (± 0.321)		
Potassium, Week 32, n=499, 498	0.04 (± 0.364)	0.00 (± 0.340)		
Potassium, Week 40, n=495, 490	0.04 (± 0.351)	0.02 (± 0.334)		
Potassium, Week 48, n=493, 486	0.04 (± 0.315)	0.03 (± 0.327)		
Sodium, Week 4, n=326, 520	0.4 (± 2.02)	0.1 (± 2.11)		
Sodium, Week 8, n=510, 515	0.1 (± 2.14)	0.2 (± 2.02)		
Sodium, Week 16, n=515, 513	0.0 (± 2.00)	-0.1 (± 2.01)		
Sodium, Week 24, n=505, 503	-0.2 (± 2.07)	-0.3 (± 2.20)		
Sodium, Week 32, n=499, 498	-0.1 (± 2.10)	-0.1 (± 2.21)		
Sodium, Week 40, n=495, 490	-0.3 (± 2.09)	-0.2 (± 2.13)		
Sodium, Week 48, n=493, 486	-0.4 (± 2.02)	-0.3 (± 2.21)		
Urea, Week 4, n=326, 520	0.24 (± 1.251)	0.19 (± 1.227)		
Urea, Week 8, n=510, 515	0.07 (± 1.306)	0.19 (± 1.336)		
Urea, Week 16, n=515, 513	0.07 (± 1.372)	0.15 (± 1.320)		
Urea, Week 24, n=505, 503	0.06 (± 1.298)	0.15 (± 1.270)		
Urea, Week 32, n=499, 498	0.11 (± 1.297)	0.16 (± 1.356)		
Urea, Week 40, n=495, 490	0.18 (± 1.345)	0.21 (± 1.412)		
Urea, Week 48, n=493, 486	0.13 (± 1.350)	0.14 (± 1.457)		

Notes:

[37] - Safety Population.

[38] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: cholesterol, glucose, direct high density lipoprotein (HDL) cholesterol, LDL cholesterol calculation and triglycerides at Week 48

End point title	Change from Baseline in clinical chemistry parameters: cholesterol, glucose, direct high density lipoprotein (HDL) cholesterol, LDL cholesterol calculation and triglycerides at Week 48

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: cholesterol, glucose, direct HDL cholesterol, LDL cholesterol calculation and triglycerides. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[39]	523[40]		
Units: Millimoles per liter				
arithmetic mean (standard deviation)				

Cholesterol, Week 48, n=423, 408	0.023 (± 0.742)	0.075 (± 0.748)		
Glucose, Week 48, n=478, 470	0.16 (± 0.907)	0.12 (± 1.208)		
Direct HDL cholesterol, Week 48, n=423, 408	0.011 (± 0.292)	-0.000 (± 0.288)		
LDL cholesterol calculation, Week 48, n=415, 398	0.026 (± 0.629)	0.098 (± 0.585)		
Triglycerides, Week 48, n=423, 408	-0.039 (± 0.790)	-0.017 (± 0.880)		

Notes:

[39] - Safety Population.

[40] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameter: GFR from creatinine adjusted using Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) over time

End point title	Change from Baseline in clinical chemistry parameter: GFR from creatinine adjusted using Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) over time

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: GFR from creatinine adjusted using CKD-EPI. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[41]	523[42]		
Units: milliliters/minute/1.73 square meter				
arithmetic mean (standard deviation)				
Week 4, n=326, 521	-0.8 (± 9.05)	0.4 (± 7.91)		
Week 8, n=508, 514	1.0 (± 9.07)	0.4 (± 8.62)		
Week 16, n=515, 513	-0.2 (± 9.08)	-0.4 (± 9.01)		
Week 24, n=503, 503	-0.7 (± 9.67)	-1.7 (± 10.65)		
Week 32, n=499, 498	-1.7 (± 10.12)	-3.0 (± 10.19)		
Week 40, n=494, 489	-1.7 (± 9.92)	-2.9 (± 9.95)		
Week 48, n=493, 486	-1.9 (± 9.96)	-3.3 (± 9.79)		

Notes:

[41] - Safety Population.

[42] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameter: Lipase over time

End point title	Change from Baseline in clinical chemistry parameter: Lipase over time

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: Lipase. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[43]	523[44]		
Units: Units per liter				
arithmetic mean (standard deviation)				
Week 4, n=326, 521	1.7 (± 28.76)	1.1 (± 22.67)		
Week 8, n=510, 514	1.5 (± 23.82)	1.4 (± 24.74)		
Week 16, n=515, 513	2.7 (± 33.41)	0.7 (± 18.82)		
Week 24, n=503, 503	0.7 (± 19.71)	2.6 (± 34.49)		
Week 32, n=499, 498	3.1 (± 35.20)	-0.5 (± 21.91)		
Week 40, n=494, 486	1.3 (± 23.35)	2.7 (± 30.95)		
Week 48, n=493, 486	3.2 (± 53.46)	2.9 (± 42.61)		

Notes:

[43] - Safety Population.

[44] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameters: basophils, eosinophils, leukocytes, lymphocytes, monocytes, neutrophils and platelets over time

End point title	Change from Baseline in hematology parameters: basophils, eosinophils, leukocytes, lymphocytes, monocytes, neutrophils and platelets over time

End point description:

Blood samples were collected for the analysis of hematology parameters: basophils, eosinophils, leukocytes, lymphocytes, monocytes, neutrophils and platelets. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[45]	523[46]		
Units: 10^9 cells per liter				
arithmetic mean (standard deviation)				
Basophils, Week 4, n=330, 516	0.006 (± 0.02751)	0.003 (± 0.02811)		
Basophils, Week 8, n=506, 505	0.000 (± 0.02682)	0.002 (± 0.02699)		
Basophils, Week 16, n=508, 507	-0.000 (± 0.02651)	0.001 (± 0.02929)		
Basophils, Week 24, n=497, 495	0.002 (± 0.02809)	0.002 (± 0.02803)		
Basophils, Week 32, n=489, 486	0.005 (± 0.02708)	0.003 (± 0.02988)		
Basophils, Week 40, n=479, 472	0.004 (± 0.02716)	0.004 (± 0.02772)		
Basophils, Week 48, n=486, 478	0.005 (± 0.02730)	0.003 (± 0.02926)		
Eosinophils, Week 4, n=330, 516	0.031 (± 0.13775)	0.015 (± 0.15112)		
Eosinophils, Week 8, n=506, 505	0.015 (± 0.14391)	0.012 (± 0.13314)		
Eosinophils, Week 16, n=508, 507	0.001 (± 0.13474)	0.010 (± 0.13012)		
Eosinophils, Week 24, n=497, 495	0.001 (± 0.13607)	0.009 (± 0.12836)		
Eosinophils, Week 32, n=489, 486	0.005 (± 0.12762)	0.011 (± 0.13810)		
Eosinophils, Week 40, n=479, 472	0.006 (± 0.13578)	0.009 (± 0.12297)		
Eosinophils, Week 48, n=486, 478	0.001 (± 0.12444)	0.002 (± 0.12646)		
Leukocytes, Week 4, n=331, 520	0.437 (± 1.5653)	0.335 (± 1.6343)		
Leukocytes, Week 8, n=508, 507	0.110 (± 1.5863)	0.214 (± 1.6109)		
Leukocytes, Week 16, n=509, 507	0.050 (± 1.4281)	0.139 (± 1.6384)		
Leukocytes, Week 24, n=499, 497	0.148 (± 1.5229)	0.139 (± 1.6301)		
Leukocytes, Week 32, n=491, 489	0.185 (± 1.5455)	0.111 (± 1.6454)		
Leukocytes, Week 40, n=480, 476	0.177 (± 1.6601)	0.100 (± 1.8042)		
Leukocytes, Week 48, n=488, 478	-0.007 (± 1.5561)	-0.012 (± 1.6035)		
Lymphocytes, Week 4, n=330, 516	0.187 (± 0.44013)	0.063 (± 0.42683)		
Lymphocytes, Week 8, n=506, 505	0.040 (± 0.39452)	0.039 (± 0.44987)		
Lymphocytes, Week 16, n=508, 507	0.060 (± 0.43470)	0.033 (± 0.44030)		
Lymphocytes, Week 24, n=497, 495	0.081 (± 0.41863)	0.061 (± 0.46240)		

Lymphocytes, Week 32, n=489, 486	0.119 (± 0.46387)	0.096 (± 0.45178)		
Lymphocytes, Week 40, n=479, 472	0.126 (± 0.44614)	0.107 (± 0.50590)		
Lymphocytes, Week 48, n=486, 478	0.063 (± 0.43255)	0.049 (± 0.48991)		
Monocytes, Week 4, n=330, 516	0.051 (± 0.14208)	0.021 (± 0.13359)		
Monocytes, Week 8, n=506, 505	0.003 (± 0.12080)	0.003 (± 0.14270)		
Monocytes, Week 16, n=508, 507	-0.002 (± 0.12804)	-0.007 (± 0.14361)		
Monocytes, Week 24, n=497, 495	0.019 (± 0.13460)	0.020 (± 0.14458)		
Monocytes, Week 32, n=489, 486	0.048 (± 0.13969)	0.039 (± 0.14531)		
Monocytes, Week 40, n=479, 472	0.060 (± 0.13570)	0.060 (± 0.15692)		
Monocytes, Week 48, n=486, 478	0.030 (± 0.13329)	0.033 (± 0.13116)		
Neutrophils, Week 4, n=330, 516	0.152 (± 1.44916)	0.228 (± 1.48979)		
Neutrophils, Week 8, n=506, 505	0.035 (± 1.49397)	0.141 (± 1.48054)		
Neutrophils, Week 16, n=508, 507	-0.018 (± 1.34384)	0.082 (± 1.52187)		
Neutrophils, Week 24, n=497, 495	0.047 (± 1.36697)	0.027 (± 1.46192)		
Neutrophils, Week 32, n=489, 486	0.001 (± 1.43051)	-0.054 (± 1.53192)		
Neutrophils, Week 40, n=479, 472	-0.021 (± 1.53092)	-0.090 (± 1.58850)		
Neutrophils, Week 48, n=486, 478	-0.108 (± 1.39875)	-0.118 (± 1.37189)		
Platelets, Week 4, n=329, 518	2.09 (± 32.330)	5.91 (± 39.613)		
Platelets, Week 8, n=506, 507	-0.62 (± 35.873)	0.27 (± 34.345)		
Platelets, Week 16, n=498, 505	0.01 (± 35.207)	-1.70 (± 34.072)		
Platelets, Week 24, n=496, 496	0.26 (± 36.085)	-2.53 (± 35.214)		
Platelets, Week 32, n=487, 486	1.67 (± 40.601)	-1.76 (± 37.490)		
Platelets, Week 40, n=478, 472	0.38 (± 38.636)	0.32 (± 38.028)		
Platelets, Week 48, n=489, 474	0.06 (± 39.549)	-1.51 (± 35.440)		

Notes:

[45] - Safety Population.

[46] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: erythrocyte mean corpuscular volume (MCV) over time

End point title	Change from Baseline in hematology parameter: erythrocyte mean corpuscular volume (MCV) over time

End point description:

Blood samples were collected for the analysis of hematology parameter: erythrocyte MCV. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[47]	523[48]		
Units: Femtoliters				
arithmetic mean (standard deviation)				
Week 4, n=331, 520	-0.32 (± 2.136)	-0.13 (± 2.322)		
Week 8, n=509, 510	-1.16 (± 3.270)	-0.84 (± 3.132)		
Week 16, n=509, 507	-1.99 (± 4.583)	-1.84 (± 4.370)		
Week 24, n=500, 498	-2.46 (± 5.085)	-2.41 (± 4.777)		
Week 32, n=491, 491	-3.17 (± 5.005)	-2.75 (± 4.682)		
Week 40, n=481, 476	-3.35 (± 4.740)	-3.15 (± 4.578)		
Week 48, n=489, 478	-3.28 (± 5.000)	-3.08 (± 4.797)		

Notes:

[47] - Safety Population.

[48] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: erythrocytes over time

End point title	Change from Baseline in hematology parameter: erythrocytes over time

End point description:

Blood samples were collected for the analysis of hematology parameter: erythrocytes. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[49]	523[50]		
Units: 10^12 cells per liter				
arithmetic mean (standard deviation)				
Week 4, n=331, 520	0.033 (± 0.2206)	0.024 (± 0.2211)		
Week 8, n=509, 510	0.092 (± 0.2669)	0.083 (± 0.2651)		
Week 16, n=509, 507	0.182 (± 0.3050)	0.162 (± 0.3222)		
Week 24, n=500, 498	0.209 (± 0.3071)	0.170 (± 0.3225)		
Week 32, n=491, 491	0.189 (± 0.3145)	0.150 (± 0.3337)		
Week 40, n=481, 476	0.229 (± 0.3217)	0.157 (± 0.3184)		
Week 48, n=489, 478	0.188 (± 0.3288)	0.170 (± 0.3329)		

Notes:

[49] - Safety Population

[50] - Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: hematocrit over time

End point title	Change from Baseline in hematology parameter: hematocrit over time

End point description:

Blood samples were collected for the analysis of hematology parameter: hematocrit. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[51]	523[52]		
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Week 4, n=331, 520	0.002 (± 0.02088)	0.002 (± 0.02202)		
Week 8, n=509, 510	0.004 (± 0.02274)	0.004 (± 0.02362)		
Week 16, n=509, 507	0.008 (± 0.02290)	0.007 (± 0.02485)		

Week 24, n=500, 498	0.008 (± 0.02219)	0.004 (± 0.02413)		
Week 32, n=491, 491	0.003 (± 0.02352)	0.001 (± 0.02469)		
Week 40, n=481, 476	0.006 (± 0.02323)	0.000 (± 0.02378)		
Week 48, n=489, 478	0.003 (± 0.02414)	0.001 (± 0.02565)		

Notes:

[51] - Safety Population

[52] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: hemoglobin over time

End point title	Change from Baseline in hematology parameter: hemoglobin over time

End point description:

Blood samples were collected for the analysis of hematology parameter: hemoglobin. Baseline value is defined as latest pre-treatment assessment with a non-missing value, including those from unscheduled visits. 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 Weeks 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[53]	523[54]		
Units: Grams per liter				
arithmetic mean (standard deviation)				
Week 4, n=331, 520	0.08 (± 6.425)	-0.16 (± 6.797)		
Week 8, n=509, 510	0.28 (± 7.028)	-0.05 (± 7.419)		
Week 16, n=509, 507	0.44 (± 6.979)	0.05 (± 7.531)		
Week 24, n=501, 498	1.48 (± 7.013)	0.45 (± 7.488)		
Week 32, n=491, 491	1.11 (± 7.633)	0.05 (± 8.041)		
Week 40, n=481, 476	1.36 (± 7.503)	-0.47 (± 7.788)		
Week 48, n=489, 478	-0.13 (± 7.631)	-0.80 (± 8.462)		

Notes:

[53] - Safety Population

[54] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with phenotypic resistance- Maintenance phase

End point title	Number of participants with phenotypic resistance- Maintenance phase

End point description:

Phenotypic resistance for following Baseline third agent drugs: Integrase inhibitors(INI):bictegravir(BIC), CAB,dolutegravir(DTG),elvitegravir(EVG),raltegravir(RAL);non-nucleoside reverse transcriptase inhibitors(NNRTI):delavirdine(DLV),efavirenz(EFV),etravirine(ETR),nevirapine(NVP),RPV; NRTI: lamivudine(3TC), abacavir(ABC), emtricitabine(FTC), tenofovir(TDF), zidovudine(ZDV), stavudine(d4T), didanosine(ddI) and protease inhibitors(PI): atazanavir(ATV), darunavir(DRV), fosamprenavir(FPV), indinavir(IDV), lopinavir(LPV), nelfinavir(NFV), ritonavir(RTV), saquinavir(SQV) and tipranavir (TPV) is presented. Phenotypic susceptibility was defined based on fold change (FC) value: resistant (FC>clinical higher cutoff or biological cutoff), partially sensitive (FC<=clinical higher cutoff and > clinical lower cutoff), sensitive(FC<=clinical lower cutoff or biological cutoff). Participants with data available at

End point type	Secondary

End point timeframe:

Up to Week 48 analysis

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8[55]	2[56]		
Units: Participants				
INI, BIC, resistant, n=6, 2	0	0		
INI, BIC, sensitive, n=6, 2	6	2		
INI, CAB, resistant, n=6, 2	3	1		
INI, CAB, sensitive, n=6, 2	3	1		
INI, DTG, resistant, n=6, 2	0	0		
INI, DTG, partially sensitive, n=6, 2	0	0		
INI, DTG, sensitive, n=6, 2	6	2		
INI, EVG, resistant, n=6, 2	4	2		
INI, EVG, sensitive, n=6, 2	2	0		
INI, RAL, resistant, n=6, 2	4	2		
INI, RAL, sensitive, n=6, 2	2	0		
NNRTI, DLV, resistant, n=7, 2	6	2		
NNRTI, DLV, sensitive, n=7, 2	1	0		
NNRTI, EFV, resistant, n=7, 2	5	2		
NNRTI, EFV, sensitive, n=7, 2	2	0		
NNRTI, ETR, resistant, n=7, 2	0	2		
NNRTI, ETR, partially sensitive, n=7, 2	4	0		
NNRTI, ETR, sensitive, n=7, 2	3	0		
NNRTI, NVP, resistant, n=7, 2	6	2		
NNRTI, NVP, sensitive, n=7, 2	1	0		
NNRTI, RPV, resistant, n=7, 2	6	2		
NNRTI, RPV, sensitive, n=7, 2	1	0		
NRTI, 3TC, resistant, n=7, 2	1	1		
NRTI, 3TC, sensitive, n=7, 2	6	1		
NRTI, ABC, resistant, n=7, 2	0	0		
NRTI, ABC, partially sensitive, n=7, 2	0	0		
NRTI, ABC, sensitive, n=7, 2	7	2		
NRTI, FTC, resistant, n=7, 2	1	1		
NRTI, FTC, sensitive, n=7, 2	6	1		

NRTI, TDF, resistant, n=7, 2	0	0		
NRTI, TDF, partially sensitive, n=7, 2	0	1		
NRTI, TDF, sensitive, n=7, 2	7	1		
NRTI, ZDV, resistant, n=7, 2	0	2		
NRTI, ZDV, sensitive, n=7, 2	7	0		
NRTI, d4T, resistant, n=7, 2	0	0		
NRTI, d4T, sensitive, n=7, 2	7	2		
NRTI, ddI, resistant, n=7, 2	0	0		
NRTI, ddI, partially sensitive, n=7, 2	0	0		
NRTI, ddI, sensitive, n=7, 2	7	2		
PI, ATV, resistant, n=7, 2	0	0		
PI, ATV, sensitive, n=7, 2	7	2		
PI, DRV, resistant, n=7, 2	0	0		
PI, DRV, partially sensitive, n=7, 2	0	0		
PI, DRV, sensitive, n=7, 2	7	2		
PI, FPV, resistant, n=7, 2	0	0		
PI, FPV, partially sensitive, n=7, 2	0	0		
PI, FPV, sensitive, n=7, 2	7	2		
PI, IDV, resistant, n=7, 2	0	0		
PI, IDV, sensitive, n=7, 2	7	2		
PI, LPV, resistant, n=7, 2	0	0		
PI, LPV, partially sensitive, n=7, 2	0	0		
PI, LPV, sensitive, n=7, 2	7	2		
PI, NFV, resistant, n=7, 2	0	1		
PI, NFV, sensitive, n=7, 2	7	1		
PI, RTV, resistant, n=7, 2	0	1		
PI, RTV, sensitive, n=7, 2	7	1		
PI, SQV, resistant, n=7, 2	0	0		
PI, SQV, partially sensitive, n=7, 2	0	0		
PI, SQV, sensitive, n=7, 2	7	2		
PI, TPV, resistant, n=7, 2	0	0		
PI, TPV, partially sensitive, n=7, 2	0	0		
PI, TPV, sensitive, n=7, 2	7	2		

Notes:

[55] - CVF Population comprised of all participants who met CVF criteria.

[56] - CVF Population comprised of all participants who met CVF criteria.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with genotypic resistance-Maintenance phase

End point title	Number of participants with genotypic resistance-Maintenance phase

End point description:

Genotypic resistance was analyzed in participants who met confirmed virologic withdrawal criteria. Genotypic Resistance data for the following Baseline third agent drugs, INI: BIC, DTG, EVG, RAL; NNRTI: DLV, EFV, ETR, NVP, RPV; NRTI: 3TC, ABC, FTC, TDF, ZDV, d4T, ddI and PI: ATV, ATV/ritonavir (r), DRV/r, FPV/r, IDV/r, LPV/r, NFV, RTV, SQV/r and TPV/r in participants meeting CVF criteria 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:

Up to Week 48 analysis

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8[57]	2[58]		
Units: Participants				
INI, BIC, resistant, n=6, 2	1	0		
INI, BIC, resistance possible, n=6, 2	2	1		
INI, BIC, sensitive, n=6, 2	3	1		
INI, DTG, resistant, n=6, 2	1	0		
INI, DTG, resistance possible, n=6, 2	2	1		
INI, DTG, sensitive, n=6, 2	3	1		
INI, EVG, resistant, n=6, 2	4	2		
INI, EVG, resistance possible, n=6, 2	0	0		
INI, EVG, sensitive, n=6, 2	2	0		
INI, RAL, resistant, n=6, 2	4	2		
INI, RAL, resistance possible, n=6, 2	0	0		
INI, RAL, sensitive, n=6, 2	2	0		
NNRTI, DLV, resistant, n=8, 2	2	1		
NNRTI, DLV, resistance possible, n=8, 2	2	1		
NNRTI, DLV, sensitive, n=8, 2	4	0		
NNRTI, EFV, resistant, n=8, 2	4	2		
NNRTI, EFV, resistance possible, n=8, 2	2	0		
NNRTI, EFV, sensitive, n=8, 2	2	0		
NNRTI, ETR, resistant, n=8, 2	0	1		
NNRTI, ETR, resistance possible, n=8, 2	2	1		
NNRTI, ETR, sensitive, n=8, 2	6	0		
NNRTI, NVP, resistant, n=8, 2	4	2		
NNRTI, NVP, resistance possible, n=8, 2	2	0		
NNRTI, NVP, sensitive, n=8, 2	2	0		
NNRTI, RPV, resistant, n=8, 2	6	1		
NNRTI, RPV, resistance possible, n=8, 2	0	0		
NNRTI, RPV, sensitive, n=8, 2	2	1		
NRTI, 3TC, resistant, n=8, 2	1	1		
NRTI, 3TC, resistance possible, n=8, 2	0	0		
NRTI, 3TC, sensitive, n=8, 2	7	1		
NRTI, ABC, resistant, n=8, 2	0	0		
NRTI, ABC, resistance possible, n=8, 2	0	1		
NRTI, ABC, sensitive, n=8, 2	8	1		
NRTI, FTC, resistant, n=8, 2	1	1		
NRTI, FTC, resistance possible, n=8, 2	0	0		
NRTI, FTC, sensitive, n=8, 2	7	1		
NRTI, TDF, resistant, n=8, 2	0	1		
NRTI, TDF, resistance possible, n=8, 2	0	0		
NRTI, TDF, sensitive, n=8, 2	8	1		
NRTI, ZDV, resistant, n=8, 2	0	1		
NRTI, ZDV, resistance possible, n=8, 2	0	0		
NRTI, ZDV, sensitive, n=8, 2	8	1		
NRTI, d4T, resistant, n=8, 2	0	1		

NRTI, d4T, resistance possible, n=8, 2	0	0		
NRTI, d4T, sensitive, n=8, 2	8	1		
NRTI, ddI, resistant, n=8, 2	0	1		
NRTI, ddI, resistance possible, n=8, 2	1	0		
NRTI, ddI, sensitive, n=8, 2	7	1		
PI, ATV, resistant, n=8, 2	0	1		
PI, ATV, resistance possible, n=8, 2	0	0		
PI, ATV, sensitive, n=8, 2	8	1		
PI, ATV/r, resistant, n=8, 2	0	0		
PI, ATV/r, resistance possible, n=8, 2	0	1		
PI, ATV/r, sensitive, n=8, 2	8	1		
PI, DRV/r, resistant, n=8, 2	0	0		
PI, DRV/r, resistance possible, n=8, 2	0	0		
PI, DRV/r, sensitive, n=8, 2	8	2		
PI, FPV/r, resistant, n=8, 2	0	0		
PI, FPV/r, resistance possible, n=8, 2	0	0		
PI, FPV/r, sensitive, n=8, 2	8	2		
PI, IDV/r, resistant, n=8, 2	0	0		
PI, IDV/r, resistance possible, n=8, 2	0	1		
PI, IDV/r, sensitive, n=8, 2	8	1		
PI, LPV/r, resistant, n=8, 2	0	0		
PI, LPV/r, resistance possible, n=8, 2	0	0		
PI, LPV/r, sensitive, n=8, 2	8	2		
PI, NFV, resistant, n=8, 2	0	1		
PI, NFV, resistance possible, n=8, 2	0	0		
PI, NFV, sensitive, n=8, 2	8	1		
PI, RTV, resistant, n=8, 2	0	1		
PI, RTV, resistance possible, n=8, 2	0	0		
PI, RTV, sensitive, n=8, 2	8	1		
PI, SQV/r, resistant, n=8, 2	0	0		
PI, SQV/r, resistance possible, n=8, 2	0	0		
PI, SQV/r, sensitive, n=8, 2	8	2		
PI, TPV/r, resistant, n=8, 2	0	1		
PI, TPV/r, resistance possible, n=8, 2	0	0		
PI, TPV/r, sensitive, n=8, 2	8	1		

Notes:

[57] - CVF Population.

[58] - CVF Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with their treatment preference as assessed using preference questionnaire at Week 48 without (w/o) prior exposure to CAB+RPV-CAB 600 mg LA +RPV 900 mg LA Q8W arm only

End point title	Number of participants with their treatment preference as assessed using preference questionnaire at Week 48 without (w/o) prior exposure to CAB+RPV-CAB 600 mg LA +RPV 900 mg LA Q8W arm only[59]

End point description:

Participants were administered the preference questionnaire which had 3 questions. For treatment preference, participants were required to provide their response to Question 1, which stated "Based on your experience which HIV treatment do you prefer". The responses included 1) Injectable LA HIV

treatment Q4W, 2) Injectable LA HIV Treatment Q8W (only select this answer if you received the 8-week injectable regimen of CAB LA + RPV LA during study), 3) Oral daily HIV treatment and 4) No preference. Oral daily HIV Treatment refers to the oral medication of CAB + RPV subjects received during the oral lead-in period. Number of participants without prior exposure to CAB+RPV who selected each of the responses based on their treatment preference is presented. Only those participants with data available at indicated time point is analyzed.

End point type	Secondary

End point timeframe:

Week 48

Notes:

[59] - 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: The endpoint is only with respect to Q8W arm where treatment preference was assessed using preference questionnaire at Week 48 without prior exposure to CABLA+RPV LA.

End point values	CAB LA + RPV LA Q8W			
Subject group type	Reporting group			
Number of subjects analysed	306[60]			
Units: Participants				
Injectable LA HIV treatment every 4 weeks	0			
Injectable LA HIV treatment every 8 weeks	300			
Oral daily HIV treatment	4			
No preference	2			

Notes:

[60] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with their treatment preference as assessed using preference questionnaire at Week 48 with >=1 weeks of prior exposure to CAB+RPV-CAB 600 mg LA +RPV 900 mg LA Q8W arm only

End point title	Number of participants with their treatment preference as assessed using preference questionnaire at Week 48 with >=1 weeks of prior exposure to CAB+RPV-CAB 600 mg LA +RPV 900 mg LA Q8W arm only[61]

End point description:

Participants were administered the preference questionnaire which had 3 questions. For treatment preference, participants were required to provide their response to Question 1, which stated "Based on your experience which HIV treatment do you prefer". The responses included 1) Injectable LA HIV treatment Q4W, 2) Injectable LA HIV Treatment Q8W (only select this answer if you received the 8-week injectable regimen of CAB LA + RPV LA during study), 3) Oral daily HIV treatment and 4) No preference. Oral daily HIV Treatment refers to the oral medication of CAB + RPV subjects received during the oral lead-in period. Number of participants with >=1 weeks of prior exposure to CAB+RPV who selected each of the responses based on their treatment preference is presented. Only those participants with data available at indicated time point is analyzed.

End point type	Secondary

End point timeframe:

Week 48

Notes:

[61] - 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: The endpoint is only with respect to Q8W arm where treatment preference was assessed

using preference questionnaire at Week 48 without prior exposure to CABLA+RPV LA.

End point values	CAB LA + RPV LA Q8W			
Subject group type	Reporting group			
Number of subjects analysed	191[62]			
Units: Participants				
Injectable LA HIV treatment every 4 weeks	6			
Injectable LA HIV treatment every 8 weeks	179			
Oral daily HIV treatment	4			
No preference	2			

Notes:

[62] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with their treatment preference as assessed using preference questionnaire at Week 48-CAB 400 mg LA +RPV 600 mg LA Q4W arm only

End point title	Number of participants with their treatment preference as assessed using preference questionnaire at Week 48-CAB 400 mg LA +RPV 600 mg LA Q4W arm only[63]

End point description:

Participants were administered the preference questionnaire which had 3 questions. For treatment preference, participants were required to provide their response to Question 1, which stated "Based on your experience which HIV treatment do you prefer". The responses included 1) Injectable LA HIV treatment Q4W, 2) Injectable LA HIV Treatment Q8W (only select this answer if you received the 8-week injectable regimen of CAB LA + RPV LA during study), 3) Oral daily HIV treatment and 4) No preference. Oral daily HIV Treatment refers to the oral medication of CAB + RPV subjects received during the oral lead-in period. Number of participants who selected each of the responses based on their treatment preference is presented. Only those participants with data available at indicated time point is analyzed.

End point type	Secondary

End point timeframe:

Week 48

Notes:

[63] - 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: The endpoint is only with respect to Q8W arm where treatment preference was assessed using preference questionnaire at Week 48 without prior exposure to CABLA+RPV LA.

End point values	CAB LA + RPV LA Q4W			
Subject group type	Reporting group			
Number of subjects analysed	497[64]			
Units: Participants				
Injectable LA HIV treatment every 4 weeks	468			
Injectable LA HIV treatment every 8 weeks	0			
Oral daily HIV treatment	16			

No preference	13			

Notes:

[64] - 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 in participants with or without prior exposure to CAB+RPV

End point title	Change from Baseline in Life Satisfaction (LISAT) Using HIV/AIDs-targeted Quality of Life (HATQoL) Questionnaire in participants with or without prior exposure to CAB+RPV

End point description:

HATQoL questionnaire, used to assess health related QoL(HRQoL). It comprises of 3 dimensions:LISAT, medication worries(MEDWO) and disclosure worries(DISWO). Total imputed value score for LISAT is calculated on a 0-100 scale using formula:LISAT 100=[100 divided by (20 minus 4)]*(LISAT minus 4). Response of 5 shows satisfaction all of time and 1 as none of time. Higher the score, greater satisfaction to life and less worry. Transformed dimension score for each domain was summarized and analyzed. Last Observation Carried Forward(LOCF) was primary method of analysis. Data for participants w/o/with prior exposure to CAB+RPV(0 Weeks[w/o exposure] and >=1 Weeks[with exposure]) has been presented. Baseline value is defined as last available recorded value up to and including the Maintenance treatment start. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Participants with data available at specified data points were analyzed(n= X in category titles)

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Weeks 24 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[65]	523[66]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Without exposure, Week 24, n=318, 324	1.5 (± 14.87)	-0.5 (± 18.00)		
Without exposure, Week 48, n=319, 324	-0.8 (± 15.24)	0.6 (± 17.51)		
With exposure, Week 24, n=192, 194	-0.8 (± 14.31)	0.8 (± 13.73)		
With exposure, Week 48, n=192, 194	0.3 (± 14.03)	-1.3 (± 14.50)		

Notes:

[65] - ITT-E Population.

[66] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

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

Questionnaire in participants with or without prior exposure to CAB+RPV

End point title	Change from Baseline in HIV medication, MEDWO using HATQoL Questionnaire in participants with or without prior exposure to CAB+RPV

End point description:

Total imputed value score for MEDWO is calculated on a 0-100 scale using formula: MEDWO 100=[100 divided by (25 minus 5)]*(MEDWO minus 5). A response of 1 in MEDWO score shows medication worries all of the time and 5 as none of the time. The higher the score, the greater satisfaction to life and the less worry. The transformed dimension score for each domain was summarized and analyzed. LOCF was used as primary method of analysis. Participants without/with prior exposure to CAB+RPV (0 Weeks [without exposure] and >=1 Weeks [with exposure]) has been presented. Baseline value is defined as last available recorded value up to and including the Maintenance treatment start. 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 Weeks 24 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[67]	523[68]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Without exposure, Week 24, n=318, 324	2.7 (± 16.53)	2.6 (± 15.61)		
Without exposure, Week 48, n=319, 324	3.0 (± 15.87)	1.9 (± 15.97)		
With exposure, Week 24, n=192, 194	0.7 (± 10.57)	1.7 (± 14.86)		
With exposure, Week 48, n=192, 194	1.3 (± 8.82)	1.3 (± 17.95)		

Notes:

[67] - ITT-E Population

[68] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in DISWO using HATQoL Questionnaire in participants with or without prior exposure to CAB+RPV

End point title	Change from Baseline in DISWO using HATQoL Questionnaire in participants with or without prior exposure to CAB+RPV

End point description:

The total imputed value score for DISWO is calculated on a 0-100 scale using the formula: DISWO 100=[100 divided by (25 minus 5)]*(DISWO minus 5). A response of 1 in DISWO score shows disclosure worries all of the time and 5 as none of the time. The higher the score, the greater satisfaction to life and the less worry. The transformed dimension score for each domain was summarized and analyzed. LOCF was used as primary method of analysis. Participants without/with prior exposure to CAB+RPV (0 Weeks [without exposure] and >=1 Weeks [with exposure]) has been presented. Baseline value is defined as last available recorded value up to and including the Maintenance treatment start. 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 Weeks 24 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[69]	523[70]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Without exposure, Week 24, n=317, 324	1.4 (± 25.58)	1.2 (± 23.18)		
Without exposure, Week 48, n=318, 324	-0.5 (± 28.14)	-0.5 (± 23.86)		
With exposure, Week 24, n=192, 194	0.9 (± 21.13)	1.8 (± 24.20)		
With exposure, Week 48, n=192, 194	-0.6 (± 24.11)	1.5 (± 26.84)		

Notes:

[69] - ITT-E Population

[70] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in total treatment satisfaction score using HIV treatment satisfaction status questionnaire (HIVTSQs) at Weeks 24 and 48

End point title	Change from Baseline in total treatment satisfaction score using HIV treatment satisfaction status questionnaire (HIVTSQs) at Weeks 24 and 48

End point description:

The HIVTSQs treatment satisfaction questionnaire comprises of 1-12 questions and the total treatment satisfaction score is computed with items 1-11 and summed to produce a score with a possible range of 0 to 66. Higher scores represent greater treatment satisfaction as compared to the past few weeks. LOCF was used as primary method of analysis. Participants without/with prior exposure to CAB+RPV (0 Weeks [without exposure] and >=1 Weeks [with exposure]) has been presented. Baseline value is defined as last available recorded value up to and including the Maintenance treatment start. 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 Weeks 24 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[71]	523[72]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Without exposure, Week 24, n=319, 323	4.63 (± 9.818)	4.44 (± 9.709)		

Without exposure, Week 48, n=319, 323	4.42 (± 10.351)	3.55 (± 10.224)		
With exposure, Week 24, n=191, 193	0.55 (± 5.050)	0.55 (± 5.347)		
With exposure, Week 48, n=191, 194	0.40 (± 5.242)	-0.01 (± 6.521)		

Notes:

[71] - ITT-E Population

[72] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in individual item scores using HIVTSQs at Weeks 24 and 48

End point title	Change from Baseline in individual item scores using HIVTSQs at Weeks 24 and 48

End point description:

HIVTSQs is a 12 item questionnaire. The individual item scores on HIVTSQs scale are rated as 6 (very satisfied, convenient, flexible, etc.) to 0 (very dissatisfied, inconvenient, inflexible, etc.). Higher scores represent greater satisfaction with each aspect of treatment. LOCF was used as primary method of analysis. Participants without/with prior exposure to CAB+RPV (0 Weeks [without exposure] and >=1 Weeks [with exposure]) has been presented. Baseline value is defined as last available recorded value up to and including the Maintenance treatment start. 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 Weeks 24 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[73]	523[74]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Item 1, Without exposure, Week 24, n=319, 323	0.3 (± 1.19)	0.3 (± 1.18)		
Item 1, Without exposure, Week 48, n=319, 323	0.3 (± 1.23)	0.2 (± 1.27)		
Item 1, With exposure, Week 24, n=191, 193	0.1 (± 0.77)	0.0 (± 0.78)		
Item 1, With exposure, Week 48, n=191, 194	0.1 (± 0.81)	0.0 (± 0.90)		
Item 2, Without exposure, Week 24, n=319, 323	0.0 (± 0.73)	0.1 (± 0.67)		
Item 2, Without exposure, Week 48, n=319, 323	0.0 (± 0.78)	0.0 (± 0.65)		
Item 2, With exposure, Week 24, n=191, 193	0.0 (± 0.42)	0.1 (± 0.61)		
Item 2, With exposure, Week 48, n=191, 194	0.0 (± 0.49)	0.1 (± 0.63)		
Item 3, Without exposure, Week 24, n=319, 323	0.0 (± 1.42)	0.0 (± 1.49)		
Item 3, Without exposure, Week 48, n=319, 323	0.0 (± 1.45)	0.0 (± 1.48)		

Item 3, With exposure, Week 24, n=191, 193	0.0 (± 0.82)	0.1 (± 1.03)		
Item 3, With exposure, Week 48, n=191, 194	0.0 (± 1.05)	0.0 (± 1.20)		
Item 4, Without exposure, Week 24, n=319, 323	0.3 (± 1.05)	0.3 (± 1.28)		
Item 4, Without exposure, Week 48, n=319, 323	0.2 (± 1.20)	0.2 (± 1.28)		
Item 4, With exposure, Week 24, n=191, 193	0.1 (± 0.73)	0.0 (± 0.80)		
Item 4, With exposure, Week 48, n=191, 194	0.1 (± 0.73)	0.0 (± 0.98)		
Item 5, Without exposure, Week 24, n=319, 323	0.7 (± 1.41)	0.6 (± 1.37)		
Item 5, Without exposure, Week 48, n=319, 323	0.7 (± 1.36)	0.5 (± 1.42)		
Item 5, With exposure, Week 24, n=191, 193	0.0 (± 0.58)	0.1 (± 0.72)		
Item 5, With exposure, Week 48, n=191, 194	0.0 (± 0.69)	0.0 (± 0.88)		
Item 6, Without exposure, Week 24, n=319, 323	0.9 (± 1.72)	0.8 (± 1.71)		
Item 6, Without exposure, Week 48, n=319, 323	0.8 (± 1.71)	0.8 (± 1.80)		
Item 6, With exposure, Week 24, n=191, 193	0.2 (± 0.96)	0.1 (± 0.90)		
Item 6, With exposure, Week 48, n=191, 194	0.1 (± 1.13)	-0.1 (± 1.12)		
Item 7, Without exposure, Week 24, n=319, 323	0.3 (± 0.78)	0.2 (± 0.98)		
Item 7, Without exposure, Week 48, n=319, 323	0.2 (± 0.94)	0.2 (± 0.92)		
Item 7, With exposure, Week 24, n=191, 193	0.0 (± 0.55)	0.0 (± 0.70)		
Item 7, With exposure, Week 48, n=191, 194	0.1 (± 0.73)	0.1 (± 0.69)		
Item 8, Without exposure, Week 24, n=318, 322	0.5 (± 1.31)	0.6 (± 1.30)		
Item 8, Without exposure, Week 48, n=319, 323	0.5 (± 1.31)	0.5 (± 1.41)		
Item 8, With exposure, Week 24, n=191, 194	0.1 (± 0.61)	0.1 (± 0.58)		
Item 8, With exposure, Week 48, n=191, 194	0.0 (± 0.64)	0.0 (± 0.80)		
Item 9, Without exposure, Week 24, n=319, 322	0.4 (± 1.16)	0.4 (± 1.30)		
Item 9, Without exposure, Week 48, n=319, 323	0.4 (± 1.23)	0.3 (± 1.36)		
Item 9, With exposure, Week 24, n=191, 194	0.0 (± 0.52)	0.0 (± 0.72)		
Item 9, With exposure, Week 48, n=191, 194	0.1 (± 0.55)	0.0 (± 0.85)		
Item 10, Without exposure, Week 24, n=319, 322	0.8 (± 1.44)	0.9 (± 1.50)		
Item 10, Without exposure, Week 48, n=319, 323	0.8 (± 1.52)	0.7 (± 1.63)		
Item 10, With exposure, Week 24, n=191, 194	0.0 (± 0.78)	0.0 (± 0.67)		
Item 10, With exposure, Week 48, n=191, 194	0.0 (± 0.79)	0.0 (± 0.77)		
Item 11, Without exposure, Week 24, n=319, 322	0.4 (± 1.22)	0.4 (± 1.25)		

Item 11, Without exposure, Week 48, n=319, 323	0.4 (± 1.26)	0.3 (± 1.31)		
Item 11, With exposure, Week 24, n=191, 194	0.0 (± 0.73)	0.1 (± 0.65)		
Item 11, With exposure, Week 48, n=191, 194	0.0 (± 0.62)	-0.1 (± 0.84)		
Item 12, Without exposure, Week 24, n=319, 322	-0.4 (± 1.46)	-0.4 (± 1.48)		
Item 12, Without exposure, Week 48, n=319, 323	-0.3 (± 1.46)	-0.5 (± 1.57)		
Item 12, With exposure, Week 24, n=191, 194	-0.1 (± 0.92)	0.0 (± 0.92)		
Item 12, With exposure, Week 48, n=191, 194	-0.1 (± 1.08)	0.0 (± 1.02)		

Notes:

[73] - ITT-E Population

[74] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Total treatment satisfaction change score using HIV treatment satisfaction change questionnaire (HIVTSQc) at Week 48

End point title	Total treatment satisfaction change score using HIV treatment satisfaction change questionnaire (HIVTSQc) at Week 48

End point description:

The HIVTSQc is a 1-12 items questionnaire. Each item is scored -3 to 3. Total treatment satisfaction change score is computed using items 1 to 11 and are summed to produce a score with a possible range of -33 to 33. Higher the score, greater the improvement in satisfaction with treatment; the lower the score, the greater the deterioration in satisfaction with treatment. A score of 0 represented no change. LOCF was used as primary method of analysis. Total treatment satisfaction change score for participants who entered the current study from Q4W arm of ATLAS (NCT number: NCT02951052) and from either standard of care (SOC) arms of ATLAS or the new SOC participants) 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:

Week 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[75]	523[76]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Q4W ATLAS, n=124, 125	29.1 (± 6.72)	24.7 (± 12.33)		
SOC, n=380, 382	28.9 (± 7.68)	27.3 (± 9.50)		

Notes:

[75] - ITT-E Population

[76] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 8 in dimension scores using perception of injection (PIN) questionnaire.

End point title	Change from Week 8 in dimension scores using perception of injection (PIN) questionnaire.

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 an HIV injectable treatment following visit and satisfaction with mode of treatment administration of individuals receiving injection and perceptions of individuals associated with receiving injections. This measure contains 21 items that measure pain at injection site, local site reactions, impact on functioning and willingness to pursue injectable treatment outside of a clinical trial. Scores range from 1 to 5 and 1 always = most favourable perception of vaccination, and 5=most unfavourable. Dimension scores include bother from ISR, leg movement, sleep and acceptability. Domain scores is calculated as mean of all items within domain. Higher the scores, worse perception of injection. LOCF was primary method of analysis. Participants with data available at specified data points were analyzed (represented by n= X in category titles)

End point type	Secondary

End point timeframe:

Week 8 and Weeks 24 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[77]	523[78]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Bother of ISRs, Week 24, n=515, 515	-0.00 (± 0.459)	-0.01 (± 0.509)		
Bother of ISRs, Week 48, n=515, 515	-0.00 (± 0.531)	0.01 (± 0.543)		
Leg Movement, Week 24, n=515, 514	-0.11 (± 0.804)	-0.23 (± 0.809)		
Leg Movement, Week 48, n=515, 514	-0.12 (± 0.818)	-0.24 (± 0.789)		
Sleep, Week 24, n=515, 514	-0.00 (± 0.772)	-0.20 (± 0.793)		
Sleep, Week 48, n=515, 514	-0.03 (± 0.814)	-0.18 (± 0.804)		
Acceptance, Week 24, n=514, 515	-0.13 (± 0.813)	-0.13 (± 0.837)		
Acceptance, Week 48, n=514, 515	-0.18 (± 0.829)	-0.13 (± 0.880)		

Notes:

[77] - ITT-E Population

[78] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 8 in individual item scores (Anxiety before, Pain, Satisfaction, Anxiety after and Willingness) using perception of injection (PIN) questionnaire.

End point title	Change from Week 8 in individual item scores (Anxiety before,

	Pain, Satisfaction, Anxiety after and Willingness) using perception of injection (PIN) questionnaire.

End point description:

The PIN questionnaire explores the bother of pain at the injection site and ISRs, anxiety before and after injection, willingness to receive an HIV injectable treatment the following visit and satisfaction with the mode of treatment administration of individuals receiving injection and perceptions of individuals associated with receiving injections. This measure contains 21 items that measure pain at injection site, local site reactions, impact on functioning and willingness to pursue injectable treatment outside of a clinical trial. The items in the scale are rated on a 5-point scale ranging from 1(very dissatisfied, extremely, etc.) to 5 (very satisfied, not at all, etc.). Lower scores represent worse perception of injection. LOCF was used as primary method of analysis. 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:

Week 8 and Weeks 24 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[79]	523[80]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Anxiety before, Week 24, n=515, 515	0.0 (± 0.83)	-0.1 (± 0.85)		
Anxiety before, Week 48, n=515, 515	-0.1 (± 0.82)	-0.1 (± 0.85)		
Pain, Week 24, n=515, 515	0.1 (± 0.83)	0.1 (± 0.84)		
Pain, Week 48, n=515, 515	0.0 (± 0.85)	0.0 (± 0.84)		
Satisfaction, Week 24, n=514, 515	0.1 (± 0.77)	-0.0 (± 0.77)		
Satisfaction, Week 48, n=514, 515	-0.0 (± 0.77)	-0.0 (± 0.84)		
Anxiety after, Week 24, n=514, 515	-0.0 (± 0.76)	0.0 (± 0.83)		
Anxiety after, Week 48, n=514, 515	-0.1 (± 0.79)	-0.1 (± 0.89)		
Willingness, Week 24, n=514, 514	-0.1 (± 0.55)	-0.1 (± 0.65)		
Willingness, Week 48, n=514, 514	-0.0 (± 0.66)	-0.1 (± 0.72)		

Notes:

[79] - ITT-E Population

[80] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Treatment Acceptance a Using "General Acceptance" Dimension of the Chronic Treatment Acceptance (ACCEPT) Questionnaire in participants with or without prior exposure to CAB+RPV

End point title	Change from Baseline in Treatment Acceptance a Using "General Acceptance" Dimension of the Chronic Treatment Acceptance (ACCEPT) Questionnaire in participants with or without prior exposure to CAB+RPV

End point description:

ACCEPT questionnaire is a generic medication acceptance measure assessing how participants weigh advantages and disadvantages of long-term medication. It consists of 25 items that capture 6 dimensions. 3 questions that focus on general acceptance of study medication were analyzed.Items on scale are rated as 1-5 scores:1:not at all acceptable,2:not very acceptable,3:somewhat acceptable, 4:totally acceptable and 5:I don't know.Total score of dimension is mean of recoded items of dimension and then linearly transformed on a scale from 0 to 100:Total Score=(mean of recoded items in dimension minus1)divided by2*100. LOCF was primary method of analysis. Data for participants w/o or

with prior exposure has been presented.Baseline value is last available value up to and including Maintenance treatment. Change from Baseline value is value at post-dose visit minus Baseline value. 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 Weeks 24 and 48

End point values	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	522[81]	523[82]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Without exposure, Week 24, n=319, 323	6.0 (± 27.96)	4.0 (± 33.53)		
Without exposure, Week 48, n=319, 324	6.9 (± 30.96)	5.6 (± 31.77)		
With exposure, Week 24, n=192, 194	0.3 (± 21.37)	-1.7 (± 21.79)		
With exposure, Week 48, n=192, 194	-0.1 (± 24.92)	-2.7 (± 24.25)		

Notes:

[81] - ITT-E Population

[82] - ITT-E 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 pharmacokinetic (PK) analysis of CAB LA. PK Population comprises of all participants who received CAB and / or RPV and underwent PK sampling during the study and provide at least 1 non-missing CAB and / or RPV plasma concentration value (Non-quantifiable [NQ] values will be considered as non-missing values). 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 4, 8, 16, 24, 32, 40 and 48

End point values	CAB LA Q8W	CAB LA Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	521[83]	521[84]		
Units: Micrograms per milliliter				
geometric mean (confidence interval 95%)				
Pre-dose, Week 4, n=314, 513	5.1543 (4.8702 to 5.4550)	4.0285 (3.8303 to 4.2369)		

Pre-dose, Week 8, n=516, 513	1.7938 (1.7007 to 1.8920)	1.9011 (1.7965 to 2.0119)		
Pre-dose, Week 16, n=512, 514	1.5983 (1.5223 to 1.6781)	2.3358 (2.2436 to 2.4317)		
Pre-dose, Week 24, n=506, 510	1.5955 (1.5203 to 1.6744)	2.5795 (2.4826 to 2.6802)		
Pre-dose, Week 32, n=499, 498	1.7414 (1.6612 to 1.8254)	2.8529 (2.7408 to 2.9696)		
Pre-dose, Week 40, n=496, 497	1.7873 (1.7058 to 1.8727)	2.9739 (2.8713 to 3.0801)		
Pre-dose, Week 48, n=494, 486	1.6747 (1.6033 to 1.7493)	2.7449 (2.6492 to 2.8441)		

Notes:

[83] - PK Population.

[84] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Ctrough for RPV LA Evaluable

End point title	Plasma 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 4, 8, 16, 24, 32, 40 and 48

End point values	RPV LA Q8W	RPV LA Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	521[85]	521[86]		
Units: Nanograms per milliliters				
geometric mean (confidence interval 95%)				
Pre-dose, Week 4, n=315, 514	78.05 (73.32 to 83.09)	78.60 (75.03 to 82.35)		
Pre-dose, Week 8, n=515, 512	56.35 (53.73 to 59.09)	57.95 (55.09 to 60.96)		
Pre-dose, Week 16, n=512, 513	54.84 (52.55 to 57.22)	68.12 (65.15 to 71.23)		
Pre-dose, Week 24, n=506, 509	57.16 (54.77 to 59.66)	75.76 (72.64 to 79.02)		
Pre-dose, Week 32, n=498, 498	62.07 (59.54 to 64.71)	85.76 (82.35 to 89.30)		
Pre-dose, Week 40, n=497, 497	67.22 (64.58 to 69.97)	89.49 (86.22 to 92.88)		

Pre-dose, Week 48, n=495, 488	72.29 (69.50 to 75.19)	97.22 (93.49 to 101.09)		

Notes:

[85] - PK Population.

[86] - PK 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:

Blood samples were collected at indicated time points to analyze concentration in plasma for CAB LA. Participants who transitioned from ATLAS (201585 - NCT02951052) into this ATLAS-2M (207966) study had been treated with CAB + RPV for at least one year, were approaching steady state exposures, and were therefore excluded in order to focus the population analysis on those without prior exposure. Only those participants with data available at specified time points has been analyzed.

End point type	Secondary

End point timeframe:

Predose at Weeks 4, 8, 13, 24, 32, 40, 48; 1 Week post-dose at Week 9 and 41

End point values	CAB LA Q8W	CAB LA Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	321[87]	321[88]		
Units: Micrograms*hours per milliliter				
geometric mean (confidence interval 95%)	3756.03 (3648.02 to 3867.25)	2449.75 (2378.56 to 2523.07)		

Notes:

[87] - PK Population.

[88] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC for RPV LA

End point title	AUC for RPV LA

End point description:

Blood samples were collected at indicated time points to analyze concentration in plasma for RPV LA. Participants who transitioned from ATLAS (201585 - NCT02951052) into this ATLAS-2M (207966) study had been treated with CAB + RPV for at least one year, were approaching steady state exposures, and were therefore excluded in order to focus the population analysis on those without prior exposure. Only those participants with data available at specified time points has been analyzed.

End point type	Secondary

End point timeframe:

Predose at Weeks 4, 8, 13, 24, 32, 40, 48; 1 Week post-dose at Week 9 and 41

End point values	RPV LA Q8W	RPV LA Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	321[89]	320[90]		
Units: Nanograms*hours per milliliter				
geometric mean (confidence interval 95%)	126467.59 (122284.26 to 130794.04)	70306.62 (67814.64 to 72890.17)		

Notes:

[89] - PK Population.

[90] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Concentration (Cmax) in Plasma for CAB LA Evaluable

End point title	Maximum Concentration (Cmax) in Plasma for CAB LA Evaluable

End point description:

Blood samples were collected at indicated time points to analyze Cmax in plasma for CAB LA. Participants who transitioned from ATLAS (201585 - NCT02951052) into this ATLAS-2M (207966) study had been treated with CAB + RPV for at least one year, were approaching steady state exposures, and were therefore excluded in order to focus the population analysis on those without prior exposure. Only those participants with data available at specified time points has been analyzed.

End point type	Secondary

End point timeframe:

Predose at Weeks 4, 8, 13, 24, 32, 40, 48; 1 Week post-dose at Week 9 and 41

End point values	CAB LA Q8W	CAB LA Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	321[91]	321[92]		
Units: Micrograms per milliliter				
geometric mean (confidence interval 95%)	3.976 (3.839 to 4.117)	4.277 (4.140 to 4.418)		

Notes:

[91] - PK Population.

[92] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax in Plasma for RPV LA Evaluable

End point title	Cmax in Plasma for RPV LA Evaluable

End point description:

Blood samples were collected at indicated time points to analyze Cmax in plasma for RPV LA. Participants who transitioned from ATLAS (201585 - NCT02951052) into this ATLAS-2M (207966) study had been treated with CAB + RPV for at least one year, were approaching steady state exposures, and

were therefore excluded in order to focus the population analysis on those without prior exposure. Only those participants with data available at specified time points has been analyzed.

End point type	Secondary

End point timeframe:

Predose at Weeks 4, 8, 13, 24, 32, 40, 48; 1 Week post-dose at Week 9 and 41

End point values	RPV LA Q8W	RPV LA Q4W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	321[93]	320[94]		
Units: Nanograms per milliliter				
geometric mean (confidence interval 95%)	133.062 (128.452 to 137.837)	124.279 (119.825 to 128.899)		

Notes:

[93] - PK Population.

[94] - PK Population.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Participants With Different Demographic Parameters for Inter-participant Variability

End point title	Number of Participants With Different Demographic Parameters for Inter-participant 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 participant variability for pharmacokinetic parameters.

End point type	Other pre-specified

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[95]	0[96]		
Units: Participants				

Notes:

[95] - PK Population. This was an exploratory Outcome Measure. Data will not be analyzed and reported.

[96] - PK Population. This was an exploratory Outcome Measure. Data will not be analyzed and reported.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Participants With Different Demographic Parameters

for Intra-participant Variability

End point title	Number of Participants With Different Demographic Parameters for Intra-participant 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 intra participant variability for pharmacokinetic parameters.

End point type	Other pre-specified

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[97]	0[98]		
Units: Participants				

Notes:

[97] - PK Population. This was an exploratory Outcome Measure. Data will not be analyzed and reported.
[98] - PK Population. This was an exploratory Outcome Measure. Data will not be analyzed and reported.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-SAEs and SAEs were collected from the start of the treatment and up to Week 48 analysis

Adverse event reporting additional description:

Non-SAEs and SAEs were collected in Safety Population.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	CAB LA + RPV LA Q8W

Reporting group description:

Eligible participants transitioning from antiretroviral (ART) standard of care (SOC) therapy arm in the ATLAS study and randomized to receive CAB LA+RPV LA every 8 weeks in the current study were administered oral therapy with CAB 30 mg + RPV 25 mg once daily at Day 1 for 4 weeks. Participants then received intramuscular (IM) injections of CAB LA 600 mg and RPV LA 900 mg at Week 4b and Week 8 followed by injections every 8 weeks thereafter. Participants transitioned from the CAB LA+RPV LA every 4 week (Q4W) arm of ATLAS study received CAB LA 600 mg+RPV LA 900 mg intramuscular injections on Day 1, Week 8 and every 8 weeks thereafter.

Reporting group title	CAB LA + RPV LA Q4W

Reporting group description:

Eligible participants transitioning from ART SOC arm in the ATLAS study and randomized to receive CAB LA+RPV LA every 4 weeks in the current study were administered oral therapy with CAB 30 mg + RPV 25 mg once daily at Day 1 for 4 weeks. Participants then received a loading dose of CAB LA 600 mg and RPV LA 900 mg IM injections at Week 4b followed maintenance injections of CAB LA 400 mg +RPV LA 600 mg every 4 weeks thereafter. Participants transitioned from the Q4W arm of ATLAS study continued to receive CAB LA 400 mg+RPV LA 600 mg intramuscular injections administered every 4 weeks from Day 1.

Serious adverse events	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W	
Total subjects affected by serious adverse events			
subjects affected / exposed	27 / 522 (5.17%)	19 / 523 (3.63%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
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			
Chest pain			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			

Priapism			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Bipolar disorder			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug dependence			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance-induced psychotic disorder			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle fracture			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral infarction			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Disseminated intravascular coagulation			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo positional			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Haemorrhoids			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 522 (0.38%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oroantral fistula			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic pseudocyst			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (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			
Intervertebral disc protrusion			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 522 (0.38%)	2 / 523 (0.38%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis B			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 522 (0.38%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal abscess			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis C			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottitis obstructive			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Escherichia coli			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infectious pleural effusion			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site abscess			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar abscess			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Septic shock			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sialoadenitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 522 (0.19%)	0 / 523 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 522 (0.00%)	1 / 523 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	CAB LA + RPV LA Q8W	CAB LA + RPV LA Q4W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	429 / 522 (82.18%)	427 / 523 (81.64%)	
Nervous system disorders			
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	35 / 522 (6.70%)	36 / 523 (6.88%)	
occurrences (all)	45	53	
General disorders and administration site conditions			
Injection site pain			
alternative assessment type: Systematic			
subjects affected / exposed	371 / 522 (71.07%)	363 / 523 (69.41%)	
occurrences (all)	2014	2568	
Injection site nodule			
alternative assessment type: Systematic			
subjects affected / exposed	54 / 522 (10.34%)	89 / 523 (17.02%)	
occurrences (all)	113	204	
Injection site induration			
alternative assessment type: Systematic			

subjects affected / exposed	41 / 522 (7.85%)	39 / 523 (7.46%)	
occurrences (all)	86	96	
Injection site discomfort			
subjects affected / exposed	36 / 522 (6.90%)	41 / 523 (7.84%)	
occurrences (all)	92	110	
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	28 / 522 (5.36%)	44 / 523 (8.41%)	
occurrences (all)	46	70	
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	32 / 522 (6.13%)	27 / 523 (5.16%)	
occurrences (all)	70	45	
Injection site pruritus			
alternative assessment type: Systematic			
subjects affected / exposed	27 / 522 (5.17%)	25 / 523 (4.78%)	
occurrences (all)	63	55	
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 522 (2.49%)	33 / 523 (6.31%)	
occurrences (all)	18	41	
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	33 / 522 (6.32%)	37 / 523 (7.07%)	
occurrences (all)	35	39	
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 522 (3.26%)	29 / 523 (5.54%)	
occurrences (all)	17	30	
Musculoskeletal and connective tissue disorders			
Back pain			
alternative assessment type: Systematic			

subjects affected / exposed	28 / 522 (5.36%)	29 / 523 (5.54%)	
occurrences (all)	32	39	
Infections and infestations			
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	71 / 522 (13.60%)	74 / 523 (14.15%)	
occurrences (all)	86	101	
Upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	50 / 522 (9.58%)	71 / 523 (13.58%)	
occurrences (all)	65	99	
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	16 / 522 (3.07%)	28 / 523 (5.35%)	
occurrences (all)	17	28	
Pharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	16 / 522 (3.07%)	28 / 523 (5.35%)	
occurrences (all)	16	31	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 September 2017	Amendment 01: The primary purpose of protocol amendment 1 is to revise the study sample size to randomize approximately 1020 participants including 510 participants per arm based on a non-inferiority margin of 4% between the CAB LA + RPV LA every 8 weeks and every 4 weeks arms. Assuming the true proportion with human immunodeficiency virus-ribonucleic acid (HIV-RNA) >=50 copies per milliliter (c/mL) is 3% for the Q8W arm and 2% for the Q4W arm, the revised sample size will provide at least 85% power to show non-inferiority at Week 48. Additional minor clarifications and corrections have been added to the protocol text.
03 July 2018	Amendment 02: Add additional interim analysis of data when all participants have completed Week 24 visit, with intent of expediting submission of study results to Health Authorities;Change objective for assessing preference for CAB LA + RPV LA every 8 weeks or CAB LA + RPV LA every 4 weeks LA compared to oral antiretroviral (ARV) and the preference for CAB LA+ RPV LA every 8 weeks compared to CAB LA + RPV LA every 4 weeks from an exploratory objective to a secondary objective. A change to supporting version of Preference questionnaire administered to participants at Week 48 (or withdrawal) is also acknowledged;Add revisions and clarifications for administration of health outcomes questionnaires;Extend exclusion criterion 28 to also exclude hereditary coagulation and platelet disorders such as hemophilia or Von Willebrand Disease;Update exclusion criterion 11 to indicate that cluster of differentiation 4 plus (CD4+) counts 200 cells per microliter(cells/µL) are not exclusionary;Offer clarification that withdrawal assessments will be performed for any participant who withdraws prematurely from Maintenance or Extension Phase. Additional guidance for participants withdrawing at Week 52 or 100 has been added;Offer guidance to monitor medications that are dependent on Organic Anion Transporters 1(OAT1) and OAT3 transport upon concomitant exposure with CAB;Specify that 2-hour post-dose electrocardiogram(ECG) should be performed at Day 1 and Week 48 only for participants receiving CAB LA+RPV LA as it is not required for those receiving oral CAB+RPV at Day1;Exclude language that previously indicated hormonal contraception may be susceptible to interaction with study drugs. Lack of a demonstrated interaction with a representative contraceptive supports use of CAB and RPV across a broad range of estrogen and progestin or progestin only hormonal contraceptives;Add minor clarifications and corrections to typographical errors/formatting to protocol text.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported