



Clinical trial results:

A Phase III, randomized, multicenter, parallel-group, non-inferiority, open-label study evaluating the efficacy, safety, and tolerability of switching to long-acting cabotegravir plus long acting rilpivirine from current INI- NNRTI-, or PI-based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2016-001647-39 |
| Trial protocol | ES DE SE IT |
| Global end of trial date | |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 |
| This version publication date | 09 June 2019 |
| First version publication date | 09 June 2019 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 201585 |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | ViiV Healthcare |
| Sponsor organisation address | 980 Great West Road, Brentford, Middlesex, United Kingdom, |
| Public contact | GSK Reponse Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact | GSK Reponse 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 | 14 September 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 29 May 2018 |
| Global end of trial reached? | No |

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferior antiviral activity of switching to intramuscular CAB LA + RPV LA every 4 weeks (monthly) compared to continuation of current first line antiretroviral regimen over 48 weeks in HIV-1 infected antiretroviral therapy (ART)- experienced participants

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 28 October 2016 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Argentina: 16 |
| Country: Number of subjects enrolled | Australia: 19 |
| Country: Number of subjects enrolled | Canada: 34 |
| Country: Number of subjects enrolled | France: 32 |
| Country: Number of subjects enrolled | Germany: 48 |
| Country: Number of subjects enrolled | Italy: 28 |
| Country: Number of subjects enrolled | Mexico: 10 |
| Country: Number of subjects enrolled | Korea, Republic of: 19 |
| Country: Number of subjects enrolled | Russian Federation: 106 |
| Country: Number of subjects enrolled | South Africa: 71 |
| Country: Number of subjects enrolled | Spain: 62 |
| Country: Number of subjects enrolled | Sweden: 15 |
| Country: Number of subjects enrolled | United States: 156 |
| Worldwide total number of subjects | 616 |
| EEA total number of subjects | 185 |

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) | 601 |
| From 65 to 84 years | 15 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

This was a phase III, randomized, open-label, active-controlled, multi-center, parallel-group, non-inferiority study to evaluate the antiviral activity and safety of two long-acting (LA) injectable drugs, cabotegravir (CAB) plus rilpivirine (RPV) when compared to current standard of care conducted in virologically suppressed human immunodeficiency.

Pre-assignment

Screening details:

A total of 618 participants were enrolled in the study. Two randomized participants did not receive study treatment. A total of 616 participants contributed to the Intent-to-treat exposed Population and Safety Population. The results presented are based on Week 48 primary analysis.

Period 1

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

Arms

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

Arm description:

During Maintenance phase (Day 1-Week 52), participants received oral CAB 30 milligram (mg)+RPV 25 mg once daily from Day 1 for 4 weeks. At Week 4B, the participants were given the last dose of oral CAB+RPV and the first dose of CAB LA 600 mg+RPV LA 900 mg injections within 2 hours of the final oral dose. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg every four weeks (Q4W) through Week 52. After completion of Maintenance phase, participants who chose to enter Extension phase continued to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up period

| | |
|--|--------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Carbotegravir oral |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | 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 | Rilpivirine oral |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Buccal tablet, 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

| | |
|--|-------------------------|
| Investigational medicinal product name | Carbotegravir Injection |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | 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 milliliter(mL) injections every 4 weeks from Week 8 to Week 52 | |
| Investigational medicinal product name | Rilpivirine Injection |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | 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 every 4 weeks from Week 8 to Week 52 | |
| Arm title | Current ART |

Arm description:

During Maintenance phase (Day 1 - Week 52), participants continued to receive current antiretroviral therapy (ART) (protease inhibitor [PI] or integrase inhibitor [INI] or non-nucleoside reverse transcriptase inhibitor [NNRTI]) plus 2 NRTIs for 52 weeks. After completion of the Maintenance phase, participants who chose to enter the Extension phase switched to CAB LA+RPV LA

| | |
|--|-------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Current anti-retroviral |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Participants received 2 NRTIs + INI or 2 NRTIs + NNRTI or 2 NRTIs + PI once daily from Day 1 to Week 52.

| Number of subjects in period 1 | CAB LA+RPV LA (Q4W) | Current ART |
|---|---------------------|-------------|
| Started | 308 | 308 |
| Completed | 281 | 290 |
| Not completed | 27 | 18 |
| Adverse event, serious fatal | - | 1 |
| Consent withdrawn by subject | 1 | 5 |
| Physician decision | 2 | - |
| Adverse event, non-fatal | 13 | 4 |
| Ongoing | 1 | - |
| Protocol-specified withdrawal criterion | 1 | - |
| Lost to follow-up | 1 | 1 |
| Protocol deviation | 5 | 3 |
| Lack of efficacy | 3 | 4 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------------|
| Reporting group title | CAB LA+RPV LA (Q4W) |
|-----------------------|---------------------|

Reporting group description:

During Maintenance phase (Day 1-Week 52), participants received oral CAB 30 milligram (mg)+RPV 25 mg once daily from Day 1 for 4 weeks. At Week 4B, the participants were given the last dose of oral CAB+RPV and the first dose of CAB LA 600 mg+RPV LA 900 mg injections within 2 hours of the final oral dose. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg every four weeks (Q4W) through Week 52. After completion of Maintenance phase, participants who chose to enter Extension phase continued to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up period

| | |
|-----------------------|-------------|
| Reporting group title | Current ART |
|-----------------------|-------------|

Reporting group description:

During Maintenance phase (Day 1 - Week 52), participants continued to receive current antiretroviral therapy (ART) (protease inhibitor [PI] or integrase inhibitor [INI] or non-nucleoside reverse transcriptase inhibitor [NNRTI]) plus 2 NRTIs for 52 weeks. After completion of the Maintenance phase, participants who chose to enter the Extension phase switched to CAB LA+RPV LA

| Reporting group values | CAB LA+RPV LA (Q4W) | Current ART | Total |
|--|---------------------|-------------|-------|
| Number of subjects | 308 | 308 | 616 |
| 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) | 303 | 298 | 601 |
| From 65-84 years | 5 | 10 | 15 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous Units: Years | | | |
| arithmetic mean | 41.6 | 43.2 | |
| standard deviation | ± 9.99 | ± 11.43 | - |
| Sex: Female, Male Units: Subjects | | | |
| Female | 99 | 104 | 203 |
| Male | 209 | 204 | 413 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| American Indian (AI) or Alaska Native (AN) | 8 | 8 | 16 |
| Asian-Central South Asian Heritage | 1 | 0 | 1 |
| Asian-Japanese/East/South-East Asian Heritage | 21 | 13 | 34 |
| Black or African American | 62 | 77 | 139 |
| Native Hawaiian or other Pacific Islander | 0 | 1 | 1 |

| | | | |
|--|-----|-----|-----|
| White | 214 | 207 | 421 |
| AI or AN & Black/African American | 0 | 1 | 1 |
| AI or AN & Black/African American & White | 1 | 1 | 2 |
| Black/African American or White | 1 | 0 | 1 |

End points

End points reporting groups

| | |
|-----------------------|---------------------|
| Reporting group title | CAB LA+RPV LA (Q4W) |
|-----------------------|---------------------|

Reporting group description:

During Maintenance phase (Day 1-Week 52), participants received oral CAB 30 milligram (mg)+RPV 25 mg once daily from Day 1 for 4 weeks. At Week 48, the participants were given the last dose of oral CAB+RPV and the first dose of CAB LA 600 mg+RPV LA 900 mg injections within 2 hours of the final oral dose. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg every four weeks (Q4W) through Week 52. After completion of Maintenance phase, participants who chose to enter Extension phase continued to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up period

| | |
|-----------------------|-------------|
| Reporting group title | Current ART |
|-----------------------|-------------|

Reporting group description:

During Maintenance phase (Day 1 - Week 52), participants continued to receive current antiretroviral therapy (ART) (protease inhibitor [PI] or integrase inhibitor [INI] or non-nucleoside reverse transcriptase inhibitor [NNRTI]) plus 2 NRTIs for 52 weeks. After completion of the Maintenance phase, participants who chose to enter the Extension phase switched to CAB LA+RPV LA

| | |
|----------------------------|--------|
| Subject analysis set title | CAB LA |
|----------------------------|--------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

Subject analysis set description:

Participants received IM injections of CAB LA 400 mg every four weeks through Week 52.

| | |
|----------------------------|--------|
| Subject analysis set title | RPV LA |
|----------------------------|--------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

Subject analysis set description:

Participants received IM injections of RPV LA 900 mg every four weeks through Week 52.

Primary: Number of participants with virologic failure (HIV-1 ribonucleic acid [RNA] ≥ 50 copies per milliliter [c/mL]) using snapshot algorithm at Week 48

| | |
|-----------------|---|
| End point title | Number of participants with virologic failure (HIV-1 ribonucleic acid [RNA] ≥ 50 copies per milliliter [c/mL]) using snapshot algorithm at Week 48 |
|-----------------|---|

End point description:

Number of participants with virologic failure endpoint (HIV-1 RNA ≥ 50 c/mL) as per Food and Drug Administration (FDA) snapshot algorithm at Week 48 was assessed to demonstrate the non-inferior antiviral activity of switching to intramuscular (IM) CAB LA+RPV LA every 4 weeks compared to continuation of current ART regimen over 48 weeks in HIV-1 infected ART-experienced participants. The HIV-1 RNA ≥ 50 copies/mL per snapshot algorithm was determined by the last available on-treatment HIV-1 RNA measurement within the analysis visit window of interest. Intent-to treat exposed (ITT-E) participants included all randomized participants who received at least one dose of Investigational Product (IP) during the maintenance phase. Participants were analyzed according to the randomized treatment regardless of what treatment actually received

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Week 48

| | | | | |
|-----------------------------|---------------------|--------------------|--|--|
| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[1] | 308 ^[2] | | |
| Units: Participants | 5 | 3 | | |

Notes:

[1] - ITT-E Population.

[2] - ITT-E Population

Statistical analyses

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 1 |
|-----------------------------------|------------------------|

Statistical analysis description:

Non-inferiority in the proportion of participants with virologic failure at Week 48 (per FDA's snapshot algorithm for assessing HIV-1 RNA ≥ 50 copies/mL) can be concluded if the upper bound of a two-sided 95% confidence interval for the difference in failure rates between the two treatment arms (CAB – current ART) is not more than 6%.

| | |
|---|-----------------------------------|
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[3] |
| Parameter estimate | Adjusted difference in proportion |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.2 |
| upper limit | 2.5 |

Notes:

[3] - Adjusted difference in proportion was based on Cochran-Mantel Haenszel stratified analysis adjusting for the following Baseline stratification factors: sex at birth (Male, Female) and Baseline third agent (PI, NNRTI, INI).

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

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

End point description:

Plasma samples were collected for quantitative analysis of HIV-1 RNA. Number of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 using FDA snapshot algorithm was assessed to demonstrate antiviral and immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to continuation of current ART. The HIV-1 RNA <50 copies/mL per snapshot algorithm was determined by the last available on-treatment HIV-1 RNA measurement within the analysis visit window of interest.

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

End point timeframe:

Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|---------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[4] | 308 ^[5] | | |
| Units: Participants | 285 | 294 | | |

Notes:

[4] - ITT-E Population

[5] - ITT-E Population

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|----------------------------|------------------------|
|----------------------------|------------------------|

Statistical analysis description:

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

| | |
|---|-----------------------------------|
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[6] |
| Parameter estimate | Adjusted difference in proportion |
| Point estimate | -3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.7 |
| upper limit | 0.7 |

Notes:

[6] - Adjusted difference in proportion was based on Cochran-Mantel Haenszel stratified analysis adjusting for the following Baseline stratification factors: sex at birth (Male, Female) and Baseline third agent (PI, NNRTI, INI).

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

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

End point description:

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

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

End point timeframe:

Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|---------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[7] | 308 ^[8] | | |
| Units: Participants | 286 | 295 | | |

Notes:

[7] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with confirmed virologic failure (CVF)

| | |
|-----------------|---|
| End point title | Number of participants with confirmed virologic failure (CVF) |
|-----------------|---|

End point description:

The CVF is defined as rebound as indicated by two consecutive plasma HIV-1-RNA levels ≥ 200 copies/mL after prior suppression to < 200 copies/mL. The outcome displays only visits during which at least one new CVF occurs. Plasma samples were collected for quantitative analysis of HIV-1 RNA.

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

End point timeframe:

Weeks 8, 12, 20, 24, 32 and 40

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[9] | 308 ^[10] | | |
| Units: Participants | | | | |
| Week 8 | 1 | 0 | | |
| Week 12 | 2 | 0 | | |
| Week 20 | 2 | 2 | | |
| Week 24 | 3 | 2 | | |
| Week 32 | 3 | 3 | | |
| Week 40 | 3 | 4 | | |

Notes:

[9] - ITT-E Population

[10] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 265 ^[11] | 292 ^[12] | | |
| Units: log10 copies/mL | | | | |
| arithmetic mean (standard deviation) | 1.505 (± 0.0470) | 1.518 (± 0.1123) | | |

Notes:

[11] - ITT-E Population

[12] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|--|--|
| End point title | Change from Baseline values for plasma HIV-1 RNA |
| End point description: | |
| Plasma for quantitative HIV-1 RNA were collected at indicated time points. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as: HIV-1 RNA(log 10) at Week 48 - HIV-1 RNA(log 10) at Baseline. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline and Week 48 | |

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 265 ^[13] | 292 ^[14] | | |
| Units: log10 copies/mL | | | | |
| arithmetic mean (standard deviation) | -0.013 (± 0.1940) | 0.012 (± 0.1201) | | |

Notes:

[13] - ITT-E Population

[14] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|--|--|
| End point title | Absolute values for CD4+ lymphocyte count at Week 48 |
| End point description: | |
| Blood samples were collected and CD4+ cell count assessment by flow cyclometry was carried out to evaluate the immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to current ART. Only those participants with data available at the specified data points were analyzed | |
| End point type | Secondary |

End point timeframe:

Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 263 ^[15] | 290 ^[16] | | |
| Units: Cells per cubic millimeter | | | | |
| arithmetic mean (standard deviation) | 685.3 (± 262.97) | 716.7 (± 292.85) | | |

Notes:

[15] - ITT-E Population

[16] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Blood samples were collected and CD4+ cell count assessment by flow cyclometry was carried out to evaluate the immunologic activity of switching to IM CAB LA+RPV LA every 4 weeks compared to current ART. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value at Week 48 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 (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 263 ^[17] | 290 ^[18] | | |
| Units: Cells per cubic millimeter | | | | |
| arithmetic mean (standard deviation) | 9.9 (± 187.24) | 19.4 (± 168.80) | | |

Notes:

[17] - ITT-E Population

[18] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with disease progression

| | |
|-----------------|---|
| End point title | Number of participants with disease progression |
|-----------------|---|

End point description:

Disease progression was defined as HIV-associated conditions, acquired immunodeficiency syndrome (AIDS), and death through 48 Weeks. Data of participants who experienced disease progression to Centers for Disease Control and Prevention (CDC) Stage III or death has been presented.

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

End point timeframe:

Up to Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[19] | 308 ^[20] | | |
| Units: Participants | 8 | 8 | | |

Notes:

[19] - ITT-E Population

[20] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. 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 IP during the maintenance phase of the study (on or after Day 1 visit). Participants will be assessed according to actual treatment received.

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

End point timeframe:

Up to Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[21] | 308 ^[22] | | |
| Units: Participants | | | | |
| Any non-SAE | 263 | 117 | | |
| Any SAE | 13 | 14 | | |

Notes:

[21] - Safety Population

[22] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with severity of adverse events

| | |
|-----------------|--|
| End point title | Number of participants with severity of adverse events |
|-----------------|--|

End point description:

Severity of AEs were defined as per The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table) Version 2.0, November 2014. Severity grades for AEs were as Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (Potentially life-threatening) and Grade 5 were all deaths related to an AE.

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

End point timeframe:

Up to Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[23] | 308 ^[24] | | |
| Units: Participants | | | | |
| Grade 1 | 101 | 115 | | |
| Grade 2 | 158 | 81 | | |
| Grade 3 | 27 | 19 | | |
| Grade 4 | 8 | 4 | | |
| Grade 5 | 0 | 1 | | |

Notes:

[23] - Safety Population

[24] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[25] | 308 ^[26] | | |
| Units: 10 ⁹ cells per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Basophils, Baseline, n=308, 307 | 0.021 (± 0.0147) | 0.021 (± 0.0148) | | |
| Basophils, Week 4, n=299, 291 | 0.024 (± 0.0153) | 0.023 (± 0.0161) | | |
| Basophils, Week 8, n=216, 294 | 0.023 (± 0.0188) | 0.022 (± 0.0155) | | |
| Basophils, Week 12, n=293, 290 | 0.022 (± 0.0154) | 0.022 (± 0.0157) | | |
| Basophils, Week 16, n=274, 292 | 0.022 (± 0.0147) | 0.022 (± 0.0140) | | |
| Basophils, Week 20, n=273, 292 | 0.023 (± 0.0182) | 0.024 (± 0.0195) | | |
| Basophils, Week 24, n=277, 292 | 0.023 (± 0.0139) | 0.024 (± 0.0133) | | |
| Basophils, Week 28, n=266, 295 | 0.024 (± 0.0150) | 0.023 (± 0.0138) | | |
| Basophils, Week 32, n=262, 283 | 0.025 (± 0.0171) | 0.024 (± 0.0159) | | |
| Basophils, Week 36, n=260, 282 | 0.029 (± 0.0211) | 0.028 (± 0.0190) | | |
| Basophils, Week 40, n=258, 280 | 0.035 (± 0.0266) | 0.031 (± 0.0206) | | |
| Basophils, Week 44, n=258, 268 | 0.037 (± 0.0275) | 0.033 (± 0.0222) | | |
| Basophils, Week 48, n=246, 274 | 0.040 (± 0.0253) | 0.039 (± 0.0249) | | |
| Eosinophils, Baseline, n=308, 307 | 0.142 (± 0.1409) | 0.140 (± 0.1538) | | |
| Eosinophils, Week 4, n=299, 291 | 0.168 (± 0.1587) | 0.145 (± 0.1422) | | |
| Eosinophils, Week 8, n=216, 294 | 0.154 (± 0.1379) | 0.131 (± 0.1333) | | |
| Eosinophils, Week 12, n=293, 290 | 0.142 (± 0.1172) | 0.132 (± 0.1471) | | |
| Eosinophils, Week 16, n=274, 292 | 0.153 (± 0.1395) | 0.131 (± 0.1584) | | |
| Eosinophils, Week 20, n=273, 292 | 0.152 (± 0.1480) | 0.116 (± 0.1094) | | |
| Eosinophils, Week 24, n=277, 292 | 0.143 (± 0.1323) | 0.121 (± 0.1337) | | |
| Eosinophils, Week 28, n=266, 295 | 0.144 (± 0.1266) | 0.129 (± 0.1320) | | |
| Eosinophils, Week 32, n=262, 283 | 0.170 (± 0.1643) | 0.131 (± 0.1319) | | |
| Eosinophils, Week 36, n=260, 282 | 0.150 (± 0.1403) | 0.132 (± 0.1162) | | |
| Eosinophils, Week 40, n=258, 280 | 0.161 (± 0.1206) | 0.132 (± 0.1124) | | |
| Eosinophils, Week 44, n=258, 268 | 0.175 (± 0.1471) | 0.136 (± 0.1126) | | |
| Eosinophils, Week 48, n=246, 274 | 0.174 (± 0.1412) | 0.140 (± 0.1265) | | |
| Leukocytes, Baseline, n=308, 307 | 5.87 (± 1.928) | 5.65 (± 1.897) | | |
| Leukocytes, Week 4, n=300, 298 | 6.43 (± 2.154) | 5.81 (± 1.733) | | |
| Leukocytes, Week 8, n=217, 301 | 6.14 (± 1.875) | 5.64 (± 1.663) | | |

| | | | | |
|-----------------------------------|-----------------------|-----------------------|--|--|
| Leukocytes, Week 12, n=294, 293 | 6.24 (\pm 1.876) | 5.77 (\pm 1.751) | | |
| Leukocytes, Week 16, n=279, 295 | 6.27 (\pm 1.920) | 5.82 (\pm 1.756) | | |
| Leukocytes, Week 20, n=276, 298 | 6.27 (\pm 1.947) | 5.70 (\pm 1.721) | | |
| Leukocytes, Week 24, n=279, 294 | 6.18 (\pm 1.931) | 5.78 (\pm 1.756) | | |
| Leukocytes, Week 28, n=268, 297 | 6.08 (\pm 1.949) | 5.73 (\pm 1.637) | | |
| Leukocytes, Week 32, n=267, 288 | 6.30 (\pm 1.914) | 5.73 (\pm 1.666) | | |
| Leukocytes, Week 36, n=264, 285 | 6.14 (\pm 1.831) | 5.80 (\pm 1.968) | | |
| Leukocytes, Week 40, n=264, 286 | 6.24 (\pm 2.046) | 5.74 (\pm 1.713) | | |
| Leukocytes, Week 44, n=269, 279 | 6.15 (\pm 1.884) | 5.66 (\pm 1.745) | | |
| Leukocytes, Week 48, n=252, 282 | 6.01 (\pm 1.943) | 5.62 (\pm 1.679) | | |
| Lymphocytes, Baseline, n=308, 307 | 1.943 (\pm 0.6073) | 1.940 (\pm 0.6880) | | |
| Lymphocytes, Week 4, n=299, 291 | 2.127 (\pm 0.6942) | 2.059 (\pm 0.6929) | | |
| Lymphocytes, Week 8, n=216, 294 | 1.995 (\pm 0.6347) | 1.975 (\pm 0.6549) | | |
| Lymphocytes, Week 12, n=293, 290 | 1.984 (\pm 0.6428) | 2.026 (\pm 0.6996) | | |
| Lymphocytes, Week 16, n=274, 292 | 2.057 (\pm 0.6840) | 2.029 (\pm 0.6584) | | |
| Lymphocytes, Week 20, n=273, 292 | 2.035 (\pm 0.6140) | 2.030 (\pm 0.6906) | | |
| Lymphocytes, Week 24, n=277, 292 | 2.016 (\pm 0.6523) | 1.980 (\pm 0.6047) | | |
| Lymphocytes, Week 28, n=266, 295 | 2.049 (\pm 0.6960) | 2.016 (\pm 0.6476) | | |
| Lymphocytes, Week 32, n=262, 283 | 2.020 (\pm 0.6157) | 2.007 (\pm 0.6511) | | |
| Lymphocytes, Week 36, n=260, 282 | 1.960 (\pm 0.6009) | 1.984 (\pm 0.6444) | | |
| Lymphocytes, Week 40, n=258, 280 | 1.994 (\pm 0.6149) | 1.957 (\pm 0.6305) | | |
| Lymphocytes, Week 44, n=258, 268 | 2.016 (\pm 0.6457) | 1.970 (\pm 0.6219) | | |
| Lymphocytes, Week 48, n=246, 274 | 1.900 (\pm 0.5725) | 1.915 (\pm 0.6204) | | |
| Neutrophils, Baseline, n=308, 307 | 3.437 (\pm 1.6106) | 3.209 (\pm 1.5748) | | |
| Neutrophils, Week 4, n=299, 291 | 3.708 (\pm 1.8763) | 3.244 (\pm 1.3931) | | |
| Neutrophils, Week 8, n=216, 294 | 3.597 (\pm 1.6128) | 3.190 (\pm 1.3370) | | |
| Neutrophils, Week 12, n=293, 290 | 3.724 (\pm 1.5751) | 3.268 (\pm 1.4153) | | |
| Neutrophils, Week 16, n=274, 292 | 3.670 (\pm 1.6777) | 3.308 (\pm 1.3870) | | |
| Neutrophils, Week 20, n=273, 292 | 3.707 (\pm 1.6532) | 3.188 (\pm 1.3345) | | |
| Neutrophils, Week 24, n=277, 292 | 3.613 (\pm 1.5978) | 3.289 (\pm 1.4381) | | |
| Neutrophils, Week 28, n=266, 295 | 3.528 (\pm 1.5464) | 3.221 (\pm 1.2962) | | |
| Neutrophils, Week 32, n=262, 283 | 3.704 (\pm 1.6196) | 3.228 (\pm 1.2909) | | |
| Neutrophils, Week 36, n=260, 282 | 3.629 (\pm 1.5688) | 3.314 (\pm 1.6341) | | |
| Neutrophils, Week 40, n=258, 280 | 3.688 (\pm 1.7685) | 3.280 (\pm 1.4190) | | |
| Neutrophils, Week 44, n=258, 268 | 3.571 (\pm 1.5425) | 3.169 (\pm 1.4140) | | |

| | | | | |
|----------------------------------|------------------|------------------|--|--|
| Neutrophils, Week 48, n=246, 274 | 3.450 (± 1.5649) | 3.172 (± 1.3627) | | |
| Monocytes, Baseline, n=308, 307 | 0.353 (± 0.1745) | 0.339 (± 0.1596) | | |
| Monocytes, Week 4, n=299, 291 | 0.404 (± 0.1951) | 0.367 (± 0.1694) | | |
| Monocytes, Week 8, n=216, 294 | 0.369 (± 0.1628) | 0.358 (± 0.1875) | | |
| Monocytes, Week 12, n=293, 290 | 0.375 (± 0.1563) | 0.342 (± 0.1693) | | |
| Monocytes, Week 16, n=274, 292 | 0.364 (± 0.1537) | 0.345 (± 0.1645) | | |
| Monocytes, Week 20, n=273, 292 | 0.356 (± 0.1526) | 0.342 (± 0.1632) | | |
| Monocytes, Week 24, n=277, 292 | 0.370 (± 0.1632) | 0.341 (± 0.1632) | | |
| Monocytes, Week 28, n=266, 295 | 0.354 (± 0.1631) | 0.333 (± 0.1592) | | |
| Monocytes, Week 32, n=262, 283 | 0.378 (± 0.1629) | 0.351 (± 0.1801) | | |
| Monocytes, Week 36, n=260, 282 | 0.376 (± 0.1593) | 0.366 (± 0.1824) | | |
| Monocytes, Week 40, n=258, 280 | 0.402 (± 0.1612) | 0.359 (± 0.1823) | | |
| Monocytes, Week 44, n=258, 268 | 0.409 (± 0.1643) | 0.388 (± 0.1795) | | |
| Monocytes, Week 48, n=246, 274 | 0.407 (± 0.1600) | 0.384 (± 0.1742) | | |
| Platelets, Baseline, n=308, 308 | 231.1 (± 56.75) | 232.9 (± 59.28) | | |
| Platelets, Week 4, n=300, 298 | 233.5 (± 55.09) | 238.1 (± 61.98) | | |
| Platelets, Week 8, n=216, 298 | 227.4 (± 47.04) | 234.0 (± 61.84) | | |
| Platelets, Week 12, n=294, 290 | 230.2 (± 57.32) | 237.8 (± 64.42) | | |
| Platelets, Week 16, n=279, 294 | 226.1 (± 56.82) | 236.4 (± 61.63) | | |
| Platelets, Week 20, n=274, 297 | 226.5 (± 58.11) | 237.7 (± 61.51) | | |
| Platelets, Week 24, n=279, 292 | 224.9 (± 53.19) | 239.8 (± 64.11) | | |
| Platelets, Week 28, n=268, 295 | 224.7 (± 54.15) | 239.0 (± 62.32) | | |
| Platelets, Week 32, n=267, 289 | 226.5 (± 50.84) | 239.3 (± 59.53) | | |
| Platelets, Week 36, n=267, 284 | 229.0 (± 53.90) | 242.9 (± 66.12) | | |
| Platelets, Week 40, n=263, 288 | 230.1 (± 53.48) | 240.8 (± 61.92) | | |
| Platelets, Week 44, n=270, 286 | 235.5 (± 55.80) | 241.4 (± 61.73) | | |
| Platelets, Week 48, n=253, 281 | 230.5 (± 54.33) | 240.2 (± 62.95) | | |

Notes:

[25] - Safety Population

[26] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters: erythrocyte mean corpuscular volume

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|-----------------|--|
| End point title | Absolute values for hematology parameters: erythrocyte mean corpuscular volume |
|-----------------|--|

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[27] | 308 ^[28] | | |
| Units: Femtoliters | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline, n=308, 308 | 95.7 (± 7.97) | 96.6 (± 9.35) | | |
| Week 4, n=300, 300 | 94.6 (± 6.88) | 96.9 (± 9.31) | | |
| Week 8, n=218, 301 | 92.7 (± 5.76) | 96.8 (± 9.25) | | |
| Week 12, n=294, 293 | 91.7 (± 5.69) | 96.9 (± 9.34) | | |
| Week 16, n=280, 296 | 90.6 (± 5.48) | 96.8 (± 9.64) | | |
| Week 20, n=276, 298 | 90.3 (± 5.37) | 97.0 (± 9.63) | | |
| Week 24, n=279, 294 | 90.2 (± 5.44) | 96.9 (± 9.75) | | |
| Week 28, n=268, 297 | 90.2 (± 5.68) | 97.2 (± 9.77) | | |
| Week 32, n=268, 291 | 90.1 (± 5.55) | 96.7 (± 9.36) | | |
| Week 36, n=267, 288 | 89.8 (± 5.64) | 96.5 (± 9.08) | | |
| Week 40, n=264, 289 | 89.9 (± 5.57) | 96.5 (± 9.05) | | |
| Week 44, n=273, 286 | 89.9 (± 5.52) | 96.2 (± 9.08) | | |
| Week 48, n=255, 284 | 89.9 (± 5.58) | 96.2 (± 9.38) | | |

Notes:

[27] - Safety Population

[28] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters: erythrocytes

| | |
|-----------------|---|
| End point title | Absolute values for hematology parameters: erythrocytes |
|-----------------|---|

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[29] | 308 ^[30] | | |
| Units: 10 ¹² cells per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline, n=308, 308 | 4.55 (± 0.563) | 4.49 (± 0.570) | | |
| Week 4, n=300, 300 | 4.59 (± 0.503) | 4.45 (± 0.567) | | |
| Week 8, n=218, 301 | 4.68 (± 0.479) | 4.49 (± 0.566) | | |
| Week 12, n=294, 293 | 4.79 (± 0.464) | 4.51 (± 0.580) | | |
| Week 16, n=280, 296 | 4.84 (± 0.475) | 4.48 (± 0.549) | | |
| Week 20, n=276, 298 | 4.86 (± 0.459) | 4.48 (± 0.586) | | |
| Week 24, n=279, 294 | 4.86 (± 0.471) | 4.48 (± 0.572) | | |
| Week 28, n=268, 297 | 4.85 (± 0.456) | 4.47 (± 0.565) | | |
| Week 32, n=268, 291 | 4.84 (± 0.452) | 4.48 (± 0.550) | | |
| Week 36, n=267, 288 | 4.81 (± 0.462) | 4.49 (± 0.561) | | |
| Week 40, n=264, 289 | 4.84 (± 0.456) | 4.49 (± 0.572) | | |
| Week 44, n=273, 286 | 4.86 (± 0.448) | 4.49 (± 0.572) | | |
| Week 48, n=255, 284 | 4.81 (± 0.448) | 4.50 (± 0.600) | | |

Notes:

[29] - Safety Population

[30] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters: hemoglobin

| | |
|-----------------|---|
| End point title | Absolute values for hematology parameters: hemoglobin |
|-----------------|---|

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[31] | 308 ^[32] | | |
| Units: Grams per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline, n=308, 308 | 142.2 (± 17.24) | 141.4 (± 16.29) | | |
| Week 4, n=300, 300 | 141.7 (± 16.30) | 140.5 (± 16.44) | | |

| | | | | |
|---------------------|-----------------|-----------------|--|--|
| Week 8, n=218, 301 | 141.5 (± 16.08) | 141.2 (± 16.51) | | |
| Week 12, n=294, 293 | 142.4 (± 15.90) | 141.6 (± 16.62) | | |
| Week 16, n=280, 296 | 142.5 (± 16.19) | 140.5 (± 15.81) | | |
| Week 20, n=276, 298 | 142.6 (± 15.52) | 141.2 (± 16.62) | | |
| Week 24, n=279, 294 | 143.3 (± 15.66) | 141.6 (± 16.18) | | |
| Week 28, n=268, 297 | 142.8 (± 16.05) | 140.9 (± 15.89) | | |
| Week 32, n=268, 291 | 143.0 (± 15.42) | 141.8 (± 15.81) | | |
| Week 36, n=267, 288 | 142.7 (± 16.31) | 142.3 (± 15.72) | | |
| Week 40, n=264, 289 | 143.5 (± 15.80) | 142.4 (± 15.90) | | |
| Week 44, n=273, 286 | 143.6 (± 15.66) | 142.1 (± 16.38) | | |
| Week 48, n=255, 284 | 142.7 (± 15.93) | 142.8 (± 16.34) | | |

Notes:

[31] - Safety Population

[32] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for hematology parameters: hematocrit

| | |
|-----------------|---|
| End point title | Absolute values for hematology parameters: hematocrit |
|-----------------|---|

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[33] | 308 ^[34] | | |
| Units: Proportion of red blood cells in blood | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline, n=308, 308 | 0.4333 (± 0.04804) | 0.4305 (± 0.04454) | | |
| Week 4, n=300, 300 | 0.4325 (± 0.04570) | 0.4283 (± 0.04548) | | |
| Week 8, n=218, 301 | 0.4327 (± 0.04570) | 0.4310 (± 0.04580) | | |
| Week 12, n=294, 293 | 0.4379 (± 0.04483) | 0.4338 (± 0.04640) | | |

| | | | | |
|---------------------|--------------------|--------------------|--|--|
| Week 16, n=280, 296 | 0.4369 (± 0.04626) | 0.4304 (± 0.04418) | | |
| Week 20, n=276, 298 | 0.4378 (± 0.04476) | 0.4312 (± 0.04755) | | |
| Week 24, n=279, 294 | 0.4376 (± 0.04589) | 0.4312 (± 0.04595) | | |
| Week 28, n=268, 297 | 0.4364 (± 0.04607) | 0.4308 (± 0.04555) | | |
| Week 32, n=268, 291 | 0.4350 (± 0.04311) | 0.4299 (± 0.04431) | | |
| Week 36, n=267, 288 | 0.4311 (± 0.04462) | 0.4295 (± 0.04348) | | |
| Week 40, n=264, 289 | 0.4342 (± 0.04381) | 0.4300 (± 0.04449) | | |
| Week 44, n=273, 286 | 0.4357 (± 0.04288) | 0.4282 (± 0.04472) | | |
| Week 48, n=255, 284 | 0.4318 (± 0.04438) | 0.4286 (± 0.04465) | | |

Notes:

[33] - Safety Population

[34] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Blood samples were collected for the analysis of hematology parameters including basophil, eosinophils, leukocytes, lymphocytes, neutrophils, monocytes, and platelets at indicated timepoints. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[35] | 308 ^[36] | | |
| Units: 10 ⁹ cells per liters | | | | |
| arithmetic mean (standard deviation) | | | | |
| Basophils, Week 4, n=299, 290 | 0.003 (± 0.0202) | 0.003 (± 0.0185) | | |
| Basophils, Week 8, n=216, 293 | 0.003 (± 0.0204) | 0.000 (± 0.0181) | | |
| Basophils, Week 12, n=293, 289 | 0.002 (± 0.0205) | 0.001 (± 0.0197) | | |
| Basophils, Week 16, n=274, 291 | 0.001 (± 0.0186) | 0.001 (± 0.0181) | | |

| | | | | |
|----------------------------------|-------------------|-------------------|--|--|
| Basophils, Week 20, n=273, 291 | 0.002 (± 0.0225) | 0.002 (± 0.0212) | | |
| Basophils, Week 24, n=277, 291 | 0.002 (± 0.0169) | 0.003 (± 0.0167) | | |
| Basophils, Week 28, n=266, 294 | 0.003 (± 0.0200) | 0.002 (± 0.0181) | | |
| Basophils, Week 32, n=262, 282 | 0.005 (± 0.0199) | 0.003 (± 0.0189) | | |
| Basophils, Week 36, n=260, 281 | 0.009 (± 0.0231) | 0.007 (± 0.0217) | | |
| Basophils, Week 40, n=258, 279 | 0.014 (± 0.0292) | 0.011 (± 0.0233) | | |
| Basophils, Week 44, n=258, 267 | 0.017 (± 0.0283) | 0.012 (± 0.0239) | | |
| Basophils, Week 48, n=246, 273 | 0.019 (± 0.0273) | 0.018 (± 0.0263) | | |
| Eosinophils, Week 4, n=299, 290 | 0.026 (± 0.1394) | 0.009 (± 0.1409) | | |
| Eosinophils, Week 8, n=216, 293 | 0.015 (± 0.1278) | -0.008 (± 0.1319) | | |
| Eosinophils, Week 12, n=293, 289 | -0.003 (± 0.1155) | -0.010 (± 0.1533) | | |
| Eosinophils, Week 16, n=274, 291 | 0.009 (± 0.1246) | -0.011 (± 0.1759) | | |
| Eosinophils, Week 20, n=273, 291 | 0.009 (± 0.1410) | -0.027 (± 0.1352) | | |
| Eosinophils, Week 24, n=277, 291 | 0.002 (± 0.1228) | -0.021 (± 0.1490) | | |
| Eosinophils, Week 28, n=266, 294 | -0.002 (± 0.1298) | -0.011 (± 0.1387) | | |
| Eosinophils, Week 32, n=262, 282 | 0.022 (± 0.1629) | -0.012 (± 0.1511) | | |
| Eosinophils, Week 36, n=260, 281 | 0.002 (± 0.1413) | -0.012 (± 0.1382) | | |
| Eosinophils, Week 40, n=258, 279 | 0.019 (± 0.1319) | -0.006 (± 0.1283) | | |
| Eosinophils, Week 44, n=258, 267 | 0.032 (± 0.1388) | -0.004 (± 0.1061) | | |
| Eosinophils, Week 48, n=246, 273 | 0.032 (± 0.1321) | 0.002 (± 0.1253) | | |
| Leukocytes, Week 4, n=300, 297 | 0.54 (± 1.599) | 0.13 (± 1.544) | | |
| Leukocytes, Week 8, n=217, 300 | 0.19 (± 1.579) | -0.02 (± 1.548) | | |
| Leukocytes, Week 12, n=294, 292 | 0.35 (± 1.743) | 0.10 (± 1.571) | | |
| Leukocytes, Week 16, n=279, 294 | 0.34 (± 1.653) | 0.17 (± 1.558) | | |
| Leukocytes, Week 20, n=276, 297 | 0.46 (± 1.565) | 0.04 (± 1.529) | | |
| Leukocytes, Week 24, n=279, 293 | 0.32 (± 1.720) | 0.10 (± 1.661) | | |
| Leukocytes, Week 28, n=268, 296 | 0.25 (± 1.651) | 0.07 (± 1.471) | | |
| Leukocytes, Week 32, n=267, 287 | 0.43 (± 1.602) | 0.07 (± 1.631) | | |
| Leukocytes, Week 36, n=264, 284 | 0.33 (± 1.699) | 0.13 (± 1.821) | | |
| Leukocytes, Week 40, n=264, 285 | 0.35 (± 1.808) | 0.12 (± 1.675) | | |
| Leukocytes, Week 44, n=269, 278 | 0.22 (± 1.581) | -0.03 (± 1.561) | | |
| Leukocytes, Week 48, n=252, 281 | 0.09 (± 1.646) | -0.06 (± 1.538) | | |
| Lymphocytes, Week 4, n=299, 290 | 0.174 (± 0.5185) | 0.128 (± 0.5618) | | |
| Lymphocytes, Week 8, n=216, 293 | 0.068 (± 0.5319) | 0.023 (± 0.5250) | | |

| | | | | |
|----------------------------------|------------------------|------------------------|--|--|
| Lymphocytes, Week 12, n=293, 289 | 0.033 (\pm 0.5073) | 0.079 (\pm 0.5844) | | |
| Lymphocytes, Week 16, n=274, 291 | 0.114 (\pm 0.5596) | 0.095 (\pm 0.5389) | | |
| Lymphocytes, Week 20, n=273, 291 | 0.071 (\pm 0.5274) | 0.086 (\pm 0.5411) | | |
| Lymphocytes, Week 24, n=277, 291 | 0.079 (\pm 0.5408) | 0.049 (\pm 0.4863) | | |
| Lymphocytes, Week 28, n=266, 294 | 0.101 (\pm 0.6133) | 0.069 (\pm 0.6005) | | |
| Lymphocytes, Week 32, n=262, 282 | 0.063 (\pm 0.5392) | 0.064 (\pm 0.5757) | | |
| Lymphocytes, Week 36, n=260, 281 | 0.008 (\pm 0.5333) | 0.036 (\pm 0.5525) | | |
| Lymphocytes, Week 40, n=258, 279 | 0.020 (\pm 0.5171) | 0.035 (\pm 0.5280) | | |
| Lymphocytes, Week 44, n=258, 267 | 0.045 (\pm 0.5430) | 0.045 (\pm 0.5472) | | |
| Lymphocytes, Week 48, n=246, 273 | -0.063 (\pm 0.5528) | -0.035 (\pm 0.5115) | | |
| Neutrophils, Week 4, n=299, 290 | 0.258 (\pm 1.5445) | 0.004 (\pm 1.3601) | | |
| Neutrophils, Week 8, n=216, 293 | 0.080 (\pm 1.4401) | -0.031 (\pm 1.3599) | | |
| Neutrophils, Week 12, n=293, 289 | 0.283 (\pm 1.6227) | 0.028 (\pm 1.3884) | | |
| Neutrophils, Week 16, n=274, 291 | 0.181 (\pm 1.5415) | 0.080 (\pm 1.4451) | | |
| Neutrophils, Week 20, n=273, 291 | 0.341 (\pm 1.4475) | -0.019 (\pm 1.4228) | | |
| Neutrophils, Week 24, n=277, 291 | 0.175 (\pm 1.5883) | 0.056 (\pm 1.5091) | | |
| Neutrophils, Week 28, n=266, 294 | 0.129 (\pm 1.4052) | -0.001 (\pm 1.3377) | | |
| Neutrophils, Week 32, n=262, 282 | 0.291 (\pm 1.6015) | 0.008 (\pm 1.4430) | | |
| Neutrophils, Week 36, n=260, 281 | 0.289 (\pm 1.5702) | 0.077 (\pm 1.6758) | | |
| Neutrophils, Week 40, n=258, 279 | 0.245 (\pm 1.6621) | 0.075 (\pm 1.5336) | | |
| Neutrophils, Week 44, n=258, 267 | 0.063 (\pm 1.4874) | -0.105 (\pm 1.4587) | | |
| Neutrophils, Week 48, n=246, 273 | 0.009 (\pm 1.5413) | -0.066 (\pm 1.3969) | | |
| Monocytes, Week 4, n=299, 290 | 0.049 (\pm 0.1663) | 0.030 (\pm 0.1270) | | |
| Monocytes Week 8, n=216, 293 | 0.014 (\pm 0.1433) | 0.018 (\pm 0.1591) | | |
| Monocytes, Week 12, n=293, 289 | 0.018 (\pm 0.1553) | 0.001 (\pm 0.1367) | | |
| Monocytes, Week 16, n=274, 291 | 0.005 (\pm 0.1588) | 0.003 (\pm 0.1403) | | |
| Monocytes, Week 20, n=273, 291 | 0.003 (\pm 0.1527) | 0.004 (\pm 0.1328) | | |
| Monocytes, Week 24, n=277, 291 | 0.012 (\pm 0.1484) | 0.002 (\pm 0.1331) | | |
| Monocytes, Week 28, n=266, 294 | 0.001 (\pm 0.1548) | -0.004 (\pm 0.1343) | | |
| Monocytes, Week 32, n=262, 282 | 0.019 (\pm 0.1535) | 0.011 (\pm 0.1585) | | |
| Monocytes, Week 36, n=260, 281 | 0.016 (\pm 0.1501) | 0.024 (\pm 0.1551) | | |

| | | | | |
|--------------------------------|------------------|------------------|--|--|
| Monocytes, Week 40, n=258, 279 | 0.039 (± 0.1507) | 0.020 (± 0.1550) | | |
| Monocytes, Week 44, n=258, 267 | 0.045 (± 0.1673) | 0.045 (± 0.1539) | | |
| Monocytes, Week 48, n=246, 273 | 0.047 (± 0.1502) | 0.039 (± 0.1499) | | |
| Platelets, Week 4, n=300, 298 | 1.8 (± 38.02) | 4.3 (± 36.15) | | |
| Platelets, Week 8, n=216, 298 | -5.5 (± 31.98) | 0.7 (± 35.15) | | |
| Platelets, Week 12, n=294, 290 | -0.8 (± 40.83) | 5.5 (± 36.76) | | |
| Platelets, Week 16, n=279, 294 | -5.2 (± 40.67) | 4.3 (± 34.61) | | |
| Platelets, Week 20, n=274, 297 | -3.7 (± 36.87) | 5.5 (± 38.86) | | |
| Platelets, Week 24, n=279, 292 | -4.7 (± 35.22) | 6.7 (± 41.78) | | |
| Platelets, Week 28, n=268, 295 | -5.3 (± 35.22) | 5.4 (± 38.41) | | |
| Platelets, Week 32, n=267, 289 | -2.6 (± 36.51) | 6.5 (± 35.99) | | |
| Platelets, Week 36, n=267, 284 | -1.2 (± 37.26) | 9.8 (± 44.52) | | |
| Platelets, Week 40, n=263, 288 | 0.0 (± 40.74) | 9.7 (± 39.91) | | |
| Platelets, Week 44, n=270, 286 | 4.5 (± 38.31) | 9.2 (± 42.82) | | |
| Platelets, Week 48, n=253, 281 | 0.0 (± 38.63) | 10.4 (± 41.75) | | |

Notes:

[35] - Safety Population

[36] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Blood samples were collected for the analysis of hematology parameter including erythrocyte mean corpuscular volume at indicated timepoints. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[37] | 308 ^[38] | | |
| Units: Femtoliters | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=300, 300 | -1.1 (± 2.71) | 0.2 (± 1.82) | | |
| Week 8, n=218, 301 | -3.0 (± 4.30) | 0.1 (± 1.76) | | |
| Week 12, n=294, 293 | -3.9 (± 5.23) | 0.2 (± 2.08) | | |
| Week 16, n=280, 296 | -4.9 (± 5.86) | 0.2 (± 2.42) | | |
| Week 20, n=276, 298 | -5.3 (± 5.98) | 0.3 (± 2.88) | | |
| Week 24, n=279, 294 | -5.4 (± 5.97) | 0.3 (± 3.24) | | |

| | | | | |
|---------------------|---------------|---------------|--|--|
| Week 28, n=268, 297 | -5.5 (± 6.11) | 0.4 (± 3.46) | | |
| Week 32, n=268, 291 | -5.5 (± 6.10) | 0.1 (± 3.47) | | |
| Week 36, n=267, 288 | -5.8 (± 6.24) | -0.0 (± 3.69) | | |
| Week 40, n=264, 289 | -5.6 (± 6.21) | -0.1 (± 3.62) | | |
| Week 44, n=273, 286 | -5.8 (± 6.33) | -0.3 (± 3.68) | | |
| Week 48, n=255, 284 | -5.7 (± 6.76) | -0.4 (± 3.57) | | |

Notes:

[37] - Safety Population

[38] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: erythrocytes

| | |
|-----------------|--|
| End point title | Change from Baseline for hematology parameters: erythrocytes |
|-----------------|--|

End point description:

Blood samples were collected for the analysis of hematology parameters including erythrocytes at indicated timepoints. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[39] | 308 ^[40] | | |
| Units: 10 ¹² cells per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=300, 300 | 0.04 (± 0.255) | -0.03 (± 0.226) | | |
| Week 8, n=218, 301 | 0.14 (± 0.331) | -0.01 (± 0.249) | | |
| Week 12, n=294, 293 | 0.23 (± 0.374) | 0.01 (± 0.252) | | |
| Week 16, n=280, 296 | 0.28 (± 0.380) | -0.01 (± 0.256) | | |
| Week 20, n=276, 298 | 0.30 (± 0.408) | -0.01 (± 0.273) | | |
| Week 24, n=279, 294 | 0.32 (± 0.397) | -0.01 (± 0.246) | | |
| Week 28, n=268, 297 | 0.28 (± 0.386) | -0.01 (± 0.246) | | |
| Week 32, n=268, 291 | 0.29 (± 0.393) | -0.01 (± 0.261) | | |
| Week 36, n=267, 288 | 0.26 (± 0.401) | -0.01 (± 0.259) | | |
| Week 40, n=264, 289 | 0.27 (± 0.396) | -0.01 (± 0.260) | | |
| Week 44, n=273, 286 | 0.31 (± 0.391) | -0.01 (± 0.264) | | |

| | | | | |
|---------------------|---------------------|----------------------|--|--|
| Week 48, n=255, 284 | 0.25 (\pm 0.394) | -0.01 (\pm 0.262) | | |
|---------------------|---------------------|----------------------|--|--|

Notes:

[39] - Safety Population

[40] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: hematocrit

| | |
|-----------------|--|
| End point title | Change from Baseline for hematology parameters: hematocrit |
|-----------------|--|

End point description:

Blood samples were collected for the analysis of hematology parameters including hematocrit at indicated timepoints. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline was defined as post-dose visit value minus Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|--------------------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[41] | 308 ^[42] | | |
| Units: Proportion of red blood cells in blood | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=300, 300 | -0.0003 (\pm 0.02236) | -0.0023 (\pm 0.02194) | | |
| Week 8, n=218, 301 | 0.0007 (\pm 0.02613) | -0.0005 (\pm 0.02330) | | |
| Week 12, n=294, 293 | 0.0042 (\pm 0.02607) | 0.0020 (\pm 0.02408) | | |
| Week 16, n=280, 296 | 0.0038 (\pm 0.02509) | -0.0007 (\pm 0.02513) | | |
| Week 20, n=276, 298 | 0.0043 (\pm 0.02742) | 0.0002 (\pm 0.02613) | | |
| Week 24, n=279, 294 | 0.0052 (\pm 0.02790) | 0.0002 (\pm 0.02576) | | |
| Week 28, n=268, 297 | 0.0023 (\pm 0.02699) | 0.0002 (\pm 0.02603) | | |
| Week 32, n=268, 291 | 0.0022 (\pm 0.02872) | -0.0011 (\pm 0.02916) | | |
| Week 36, n=267, 288 | -0.0012 (\pm 0.02793) | -0.0011 (\pm 0.02797) | | |
| Week 40, n=264, 289 | -0.0001 (\pm 0.02741) | -0.0011 (\pm 0.02781) | | |
| Week 44, n=273, 286 | 0.0031 (\pm 0.02896) | -0.0025 (\pm 0.02814) | | |
| Week 48, n=255, 284 | -0.0021 (\pm 0.02717) | -0.0031 (\pm 0.02700) | | |

Notes:

[41] - Safety Population

[42] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline for hematology parameters: hemoglobin

| | |
|-----------------|--|
| End point title | Change from Baseline for hematology parameters: hemoglobin |
|-----------------|--|

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[43] | 308 ^[44] | | |
| Units: Grams per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=300, 300 | -0.4 (± 6.91) | -1.0 (± 6.73) | | |
| Week 8, n=218, 301 | -0.4 (± 8.18) | -0.6 (± 7.33) | | |
| Week 12, n=294, 293 | 0.0 (± 8.14) | -0.3 (± 7.52) | | |
| Week 16, n=280, 296 | 0.4 (± 8.22) | -1.2 (± 7.75) | | |
| Week 20, n=276, 298 | 0.3 (± 8.60) | -0.5 (± 8.55) | | |
| Week 24, n=279, 294 | 1.2 (± 8.78) | -0.0 (± 8.46) | | |
| Week 28, n=268, 297 | 0.3 (± 8.49) | -0.6 (± 8.68) | | |
| Week 32, n=268, 291 | 0.9 (± 8.94) | 0.2 (± 9.45) | | |
| Week 36, n=267, 288 | 0.7 (± 9.03) | 0.8 (± 9.32) | | |
| Week 40, n=264, 289 | 0.8 (± 8.96) | 0.7 (± 9.29) | | |
| Week 44, n=273, 286 | 1.7 (± 9.49) | 0.6 (± 9.53) | | |
| Week 48, n=255, 284 | 0.2 (± 9.26) | 0.9 (± 9.07) | | |

Notes:

[43] - Safety Population

[44] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

aminotransferase (AST) and creatinine kinase (CK)

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

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[45] | 308 ^[46] | | |
| Units: International units per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| ALT, Baseline (Day 1), n=308, 308 | 23.8 (± 13.47) | 22.4 (± 12.90) | | |
| ALT, Week 4, n=301, 303 | 24.4 (± 15.60) | 22.3 (± 11.10) | | |
| ALT, Week 8, n=229, 303 | 24.0 (± 16.85) | 24.0 (± 29.86) | | |
| ALT, Week 12, n=295, 299 | 29.0 (± 114.25) | 22.7 (± 13.48) | | |
| ALT, Week 16, n=284, 298 | 23.7 (± 22.32) | 21.8 (± 11.31) | | |
| ALT, Week 20, n=277, 302 | 23.1 (± 22.49) | 21.2 (± 10.50) | | |
| ALT, Week 24, n=284, 299 | 26.3 (± 62.05) | 21.6 (± 12.64) | | |
| ALT, Week 28, n=267, 296 | 21.1 (± 12.13) | 22.1 (± 14.62) | | |
| ALT, Week 32, n=275, 294 | 21.8 (± 12.56) | 21.8 (± 12.09) | | |
| ALT, Week 36, n=273, 292 | 23.2 (± 24.94) | 22.3 (± 12.17) | | |
| ALT, Week 40, n=270, 293 | 24.5 (± 37.39) | 22.1 (± 12.78) | | |
| ALT, Week 44, n=275, 293 | 21.6 (± 13.10) | 22.1 (± 13.67) | | |
| ALT, Week 48, n=265, 292 | 21.8 (± 13.54) | 21.7 (± 11.08) | | |
| ALP, Baseline (Day 1), n=308, 308 | 76.6 (± 28.20) | 77.5 (± 26.77) | | |
| ALP, Week 4, n=301, 303 | 70.4 (± 22.75) | 75.7 (± 25.58) | | |
| ALP, Week 8, n=229, 303 | 68.9 (± 21.98) | 78.8 (± 32.40) | | |
| ALP, Week 12, n=295, 299 | 68.9 (± 24.79) | 78.6 (± 28.87) | | |
| ALP, Week 16, n=284, 298 | 67.9 (± 19.76) | 77.3 (± 27.21) | | |
| ALP, Week 20, n=277, 302 | 67.6 (± 18.72) | 76.7 (± 25.48) | | |
| ALP, Week 24, n=284, 299 | 68.1 (± 19.15) | 77.5 (± 26.36) | | |
| ALP, Week 28, n=267, 296 | 67.6 (± 18.89) | 77.2 (± 26.72) | | |
| ALP, Week 32, n=275, 294 | 66.6 (± 19.14) | 75.8 (± 25.56) | | |
| ALP, Week 36, n=273, 292 | 66.8 (± 20.68) | 76.4 (± 25.93) | | |
| ALP, Week 40, n=270, 293 | 66.2 (± 17.58) | 76.2 (± 26.08) | | |
| ALP, Week 44, n=275, 293 | 66.1 (± 18.34) | 76.8 (± 25.82) | | |
| ALP, Week 48, n=265, 292 | 66.5 (± 18.84) | 77.1 (± 26.39) | | |
| AST, Baseline (Day 1), n=308, 308 | 23.9 (± 11.31) | 22.5 (± 10.21) | | |
| AST, Week 4, n=301, 303 | 23.2 (± 11.77) | 22.7 (± 10.93) | | |
| AST, Week 8, n=229, 303 | 24.3 (± 19.49) | 22.5 (± 12.31) | | |
| AST, Week 12, n=295, 299 | 26.1 (± 64.69) | 23.2 (± 10.61) | | |
| AST, Week 16, n=284, 298 | 24.1 (± 18.20) | 22.5 (± 8.59) | | |

| | | | | |
|----------------------------------|-------------------|------------------|--|--|
| AST, Week 20, n=277, 302 | 23.5 (± 15.23) | 22.0 (± 6.83) | | |
| AST, Week 24, n=284, 298 | 24.2 (± 22.89) | 22.5 (± 9.30) | | |
| AST, Week 28, n=267, 296 | 22.2 (± 8.72) | 22.9 (± 9.61) | | |
| AST, Week 32, n=275, 294 | 22.8 (± 13.71) | 23.2 (± 12.32) | | |
| AST, Week 36, n=273, 292 | 23.0 (± 11.27) | 22.6 (± 7.18) | | |
| AST, Week 40, n=270, 293 | 23.8 (± 14.96) | 22.5 (± 7.79) | | |
| AST, Week 44, n=275, 293 | 22.9 (± 14.82) | 22.6 (± 10.26) | | |
| AST Week 48, n=265, 292 | 22.9 (± 10.35) | 23.2 (± 9.30) | | |
| CK, Baseline (Day 1), n=308, 308 | 196.6 (± 367.30) | 160.8 (± 367.57) | | |
| CK, Week 4, n=301, 303 | 192.9 (± 437.09) | 190.6 (± 472.57) | | |
| CK, Week 8, n=229, 303 | 275.9 (± 1064.72) | 145.4 (± 141.19) | | |
| CK, Week 12, n=295, 299 | 200.7 (± 484.08) | 177.0 (± 321.29) | | |
| CK, Week 16, n=284, 298 | 253.5 (± 849.45) | 167.5 (± 286.90) | | |
| CK, Week 20, n=277, 302 | 228.4 (± 570.80) | 144.5 (± 133.32) | | |
| CK, Week 24, n=284, 299 | 193.1 (± 444.27) | 161.2 (± 241.73) | | |
| CK, Week 28, n=267, 296 | 168.8 (± 163.54) | 182.7 (± 420.44) | | |
| CK, Week 32, n=275, 294 | 216.5 (± 593.10) | 195.9 (± 489.99) | | |
| CK, Week 36, n=273, 292 | 186.4 (± 325.64) | 150.7 (± 134.40) | | |
| CK, Week 40, n=270, 293 | 235.1 (± 624.03) | 160.7 (± 179.64) | | |
| CK, Week 44, n=275, 293 | 245.5 (± 1189.35) | 149.9 (± 148.23) | | |
| CK, Week 48, n=265, 292 | 198.8 (± 398.14) | 179.0 (± 331.51) | | |

Notes:

[45] - Safety Population

[46] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[47] | 308 ^[48] | | |
| Units: Grams per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Day 1), n=308, 308 | 44.2 (± 3.12) | 44.3 (± 3.19) | | |
| Week 4, n=301, 303 | 43.7 (± 2.88) | 43.8 (± 2.87) | | |
| Week 8, n=229, 303 | 43.8 (± 3.06) | 43.7 (± 3.17) | | |
| Week 12, n=295, 299 | 43.6 (± 2.99) | 43.9 (± 3.12) | | |
| Week 16, n=284, 298 | 43.5 (± 2.77) | 43.5 (± 3.12) | | |
| Week 20, n=277, 302 | 43.4 (± 2.72) | 43.5 (± 3.07) | | |
| Week 24, n=284, 299 | 43.4 (± 2.74) | 43.5 (± 3.02) | | |
| Week 28, n=267, 296 | 43.6 (± 2.85) | 43.3 (± 3.07) | | |
| Week 32, n=275, 294 | 43.5 (± 2.83) | 43.4 (± 3.25) | | |
| Week 36, n=273, 292 | 43.3 (± 2.82) | 43.4 (± 3.07) | | |
| Week 40, n=270, 293 | 43.7 (± 2.72) | 43.4 (± 3.04) | | |
| Week 44, n=275, 293 | 43.7 (± 2.78) | 43.5 (± 3.02) | | |
| Week 48, n=265, 292 | 43.8 (± 2.74) | 44.0 (± 2.92) | | |

Notes:

[47] - Safety Population

[48] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[49] | 308 ^[50] | | |
| Units: Micromoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Bilirubin, Baseline (Day 1), n=308, 308 | 9.9 (± 9.71) | 9.2 (± 6.39) | | |
| Bilirubin, Week 4, n=301, 303 | 9.1 (± 3.98) | 8.9 (± 6.14) | | |
| Bilirubin, Week 8, n=229, 303 | 9.3 (± 4.05) | 9.4 (± 9.06) | | |
| Bilirubin, Week 12, n=295, 299 | 9.3 (± 4.45) | 9.3 (± 6.62) | | |
| Bilirubin, Week 16, n=284, 298 | 10.0 (± 10.71) | 9.1 (± 6.28) | | |
| Bilirubin, Week 20, n=277, 302 | 9.7 (± 4.28) | 9.3 (± 7.56) | | |

| | | | | |
|---|---------------------|---------------------|--|--|
| Bilirubin, Week 24, n=284, 298 | 9.3 (± 3.90) | 9.4 (± 8.38) | | |
| Bilirubin, Week 28, n=267, 296 | 9.8 (± 3.99) | 9.1 (± 7.05) | | |
| Bilirubin, Week 32, n=275, 294 | 9.8 (± 4.36) | 9.3 (± 7.05) | | |
| Bilirubin, Week 36, n=273, 292 | 9.3 (± 3.79) | 9.2 (± 7.34) | | |
| Bilirubin, Week 40, n=270, 293 | 9.6 (± 4.07) | 9.5 (± 9.04) | | |
| Bilirubin, Week 44, n=275, 293 | 9.6 (± 4.19) | 9.7 (± 8.49) | | |
| Bilirubin, Week 48, n=265, 292 | 9.7 (± 4.24) | 9.5 (± 6.36) | | |
| Direct bilirubin, Baseline (Day 1), n=308, 308 | 2.4 (± 1.35) | 2.2 (± 1.25) | | |
| Direct bilirubin, Week 4, n=301, 303 | 2.3 (± 1.04) | 2.3 (± 1.27) | | |
| Direct bilirubin, Week 8, n=229, 303 | 2.3 (± 1.08) | 2.4 (± 3.96) | | |
| Direct bilirubin, Week 12, n=295, 299 | 2.2 (± 1.03) | 2.3 (± 1.30) | | |
| Direct bilirubin, Week 16, n=284, 298 | 2.5 (± 4.98) | 2.1 (± 1.08) | | |
| Direct bilirubin, Week 20, n=277, 302 | 2.2 (± 0.95) | 2.0 (± 1.31) | | |
| Direct bilirubin, Week 24, n=284, 298 | 2.2 (± 0.99) | 2.1 (± 1.26) | | |
| Direct bilirubin, Week 28, n=267, 296 | 2.1 (± 0.94) | 2.0 (± 1.28) | | |
| Direct bilirubin, Week 32, n=275, 294 | 2.1 (± 1.00) | 2.0 (± 1.22) | | |
| Direct bilirubin, Week 36, n=273, 292 | 2.1 (± 1.11) | 2.1 (± 1.27) | | |
| Direct bilirubin, Week 40, n=270, 293 | 2.1 (± 1.08) | 2.1 (± 1.37) | | |
| Direct bilirubin, Week 44, n=275, 293 | 2.2 (± 0.95) | 2.2 (± 1.30) | | |
| Direct bilirubin, Week 48, n=265, 292 | 2.2 (± 0.92) | 2.2 (± 1.23) | | |
| Creatinine, Baseline (Day 1), n=308, 308 | 79.05 (± 16.380) | 77.83 (± 16.497) | | |
| Creatinine, Week 4, n=301, 301 | 80.17 (± 15.464) | 79.47 (± 16.284) | | |
| Creatinine, Week 8, n=229, 303 | 78.79 (± 16.122) | 79.22 (± 16.824) | | |
| Creatinine, Week 12, n=295, 299 | 78.65 (± 16.534) | 79.50 (± 17.191) | | |
| Creatinine, Week 16, n=284, 298 | 78.72 (± 15.606) | 79.51 (± 17.171) | | |
| Creatinine, Week 20, n=277, 302 | 79.75 (± 15.695) | 79.62 (± 16.909) | | |
| Creatinine, Week 24, n=284, 298 | 80.15 (± 18.478) | 79.05 (± 16.673) | | |
| Creatinine, Week 28, n=267, 296 | 80.42 (± 16.335) | 79.35 (± 16.574) | | |
| Creatinine, Week 32, n=275, 294 | 79.65 (± 15.044) | 79.69 (± 16.634) | | |
| Creatinine, Week 36, n=273, 292 | 79.73 (± 15.994) | 79.34 (± 16.527) | | |
| Creatinine, Week 40, n=270, 293 | 80.28 (± 15.856) | 79.42 (± 16.856) | | |
| Creatinine, Week 44, n=275, 293 | 79.98 (± 15.775) | 79.16 (± 16.583) | | |
| Creatinine, Week 48, n=265, 292 | 80.77 (± 16.456) | 78.65 (± 16.204) | | |

Notes:

[49] - Safety Population

[50] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

including Week 48

| | |
|-----------------|--|
| End point title | Absolute values for clinical chemistry parameters: total carbon-dioxide (CO ₂), chloride, glucose, phosphate, potassium, sodium and urea over time including Week 48 |
|-----------------|--|

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[51] | 308 ^[52] | | |
| Units: Millimoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| CO ₂ , Baseline (Day 1), n=308, 308 | 22.7 (± 2.33) | 22.6 (± 2.24) | | |
| CO ₂ , Week 4, n=301, 303 | 23.7 (± 2.49) | 23.3 (± 2.27) | | |
| CO ₂ , Week 8, n=229, 303 | 23.1 (± 2.17) | 23.2 (± 2.47) | | |
| CO ₂ , Week 12, n=295, 299 | 23.2 (± 2.14) | 23.0 (± 2.36) | | |
| CO ₂ , Week 16, n=284, 298 | 22.9 (± 2.16) | 23.0 (± 2.31) | | |
| CO ₂ , Week 20, n=277, 302 | 22.9 (± 2.16) | 22.9 (± 2.29) | | |
| CO ₂ , Week 24, n=284, 298 | 22.9 (± 2.31) | 22.8 (± 2.41) | | |
| CO ₂ , Week 28, n=267, 296 | 22.7 (± 2.42) | 22.7 (± 2.27) | | |
| CO ₂ , Week 32, n=275, 294 | 22.6 (± 2.15) | 22.8 (± 2.34) | | |
| CO ₂ , Week 36, n=273, 292 | 22.8 (± 2.19) | 23.0 (± 2.26) | | |
| CO ₂ , Week 40, n=270, 293 | 23.1 (± 2.27) | 23.0 (± 2.45) | | |
| CO ₂ , Week 44, n=275, 293 | 23.0 (± 2.19) | 23.2 (± 2.31) | | |
| CO ₂ , Week 48, n=265, 292 | 22.7 (± 2.29) | 22.9 (± 2.29) | | |
| Chloride, Baseline (Day 1), n=308, 308 | 103.8 (± 2.03) | 103.8 (± 2.39) | | |
| Chloride, Week 4, n=301, 303 | 104.3 (± 2.13) | 104.3 (± 2.22) | | |
| Chloride, Week 8, n=229, 303 | 104.3 (± 2.26) | 104.2 (± 2.40) | | |
| Chloride, Week 12, n=295, 299 | 104.2 (± 2.27) | 104.3 (± 2.24) | | |
| Chloride, Week 16, n=284, 298 | 104.5 (± 2.21) | 104.5 (± 2.28) | | |
| Chloride, Week 20, n=277, 302 | 104.7 (± 2.41) | 104.5 (± 2.38) | | |
| Chloride, Week 24, n=284, 299 | 104.5 (± 2.36) | 104.7 (± 2.30) | | |
| Chloride, Week 28, n=267, 296 | 104.8 (± 2.19) | 104.8 (± 2.36) | | |
| Chloride, Week 32, n=275, 294 | 104.7 (± 2.50) | 104.7 (± 2.31) | | |
| Chloride, Week 36, n=273, 292 | 104.8 (± 2.18) | 104.6 (± 2.36) | | |
| Chloride, Week 40, n=270, 293 | 104.7 (± 2.22) | 104.6 (± 2.61) | | |
| Chloride, Week 44, n=275, 293 | 104.6 (± 2.10) | 104.6 (± 2.27) | | |
| Chloride, Week 48, n=265, 292 | 104.4 (± 2.38) | 104.1 (± 2.37) | | |
| Glucose, Baseline (Day 1), n=301, 299 | 5.00 (± 0.714) | 5.17 (± 0.988) | | |
| Glucose, Week 4, n=216, 226 | 5.17 (± 0.747) | 5.42 (± 1.250) | | |
| Glucose, Week 8, n=153, 218 | 5.16 (± 0.990) | 5.35 (± 1.037) | | |
| Glucose, Week 12, n=206, 221 | 5.19 (± 0.965) | 5.35 (± 1.091) | | |
| Glucose, Week 16, n=209, 216 | 5.22 (± 1.163) | 5.36 (± 1.317) | | |

| | | | | |
|---|------------------|------------------|--|--|
| Glucose, Week 20, n=194, 221 | 5.20 (± 0.736) | 5.37 (± 1.209) | | |
| Glucose, Week 24, n=215, 229 | 5.24 (± 0.810) | 5.35 (± 0.840) | | |
| Glucose, Week 28, n=190, 226 | 5.16 (± 0.697) | 5.36 (± 0.876) | | |
| Glucose, Week 32, n=194, 219 | 5.33 (± 1.042) | 5.45 (± 1.102) | | |
| Glucose, Week 36, n=191, 220 | 5.19 (± 0.777) | 5.40 (± 1.507) | | |
| Glucose, Week 40, n=195, 218 | 5.30 (± 0.797) | 5.44 (± 1.227) | | |
| Glucose, Week 44, n=193, 213 | 5.22 (± 0.887) | 5.44 (± 1.317) | | |
| Glucose, Week 48, n=242, 277 | 5.08 (± 0.614) | 5.22 (± 0.963) | | |
| Phosphate, Baseline (Day 1), n=308, 308 | 1.042 (± 0.1771) | 1.051 (± 0.1722) | | |
| Phosphate, Week 4, n=301, 303 | 1.110 (± 0.1793) | 1.066 (± 0.1773) | | |
| Phosphate, Week 8, n=229, 303 | 1.097 (± 0.1944) | 1.042 (± 0.1843) | | |
| Phosphate, Week 12, n=295, 299 | 1.080 (± 0.1872) | 1.062 (± 0.1922) | | |
| Phosphate, Week 16, n=284, 298 | 1.081 (± 0.1796) | 1.052 (± 0.1724) | | |
| Phosphate, Week 20, n=277, 302 | 1.073 (± 0.1746) | 1.061 (± 0.1873) | | |
| Phosphate, Week 24, n=284, 299 | 1.082 (± 0.1788) | 1.057 (± 0.1849) | | |
| Phosphate, Week 28, n=267, 296 | 1.072 (± 0.1714) | 1.053 (± 0.1741) | | |
| Phosphate, Week 32, n=275, 294 | 1.061 (± 0.1730) | 1.054 (± 0.1761) | | |
| Phosphate, Week 36, n=273, 292 | 1.052 (± 0.1700) | 1.049 (± 0.1798) | | |
| Phosphate, Week 40, n=270, 293 | 1.065 (± 0.1789) | 1.046 (± 0.1763) | | |
| Phosphate, Week 44, n=275, 293 | 1.066 (± 0.1798) | 1.052 (± 0.1902) | | |
| Phosphate, Week 48, n=265, 292 | 1.077 (± 0.1816) | 1.052 (± 0.1834) | | |
| Potassium, Baseline (Day 1), n=308, 308 | 4.16 (± 0.281) | 4.17 (± 0.314) | | |
| Potassium, Week 4, n=301, 303 | 4.21 (± 0.307) | 4.28 (± 0.352) | | |
| Potassium, Week 8, n=229, 303 | 4.16 (± 0.296) | 4.22 (± 0.393) | | |
| Potassium, Week 12, n=295, 299 | 4.19 (± 0.330) | 4.24 (± 0.332) | | |
| Potassium, Week 16, n=284, 298 | 4.18 (± 0.316) | 4.23 (± 0.321) | | |
| Potassium, Week 20, n=277, 302 | 4.19 (± 0.311) | 4.21 (± 0.320) | | |
| Potassium, Week 24, n=284, 298 | 4.18 (± 0.287) | 4.23 (± 0.337) | | |
| Potassium, Week 28, n=267, 296 | 4.19 (± 0.346) | 4.24 (± 0.391) | | |
| Potassium, Week 32, n=275, 294 | 4.18 (± 0.368) | 4.21 (± 0.341) | | |
| Potassium, Week 36, n=273, 292 | 4.19 (± 0.326) | 4.23 (± 0.345) | | |
| Potassium, Week 40, n=270, 293 | 4.20 (± 0.301) | 4.23 (± 0.322) | | |
| Potassium, Week 44, n=275, 293 | 4.21 (± 0.323) | 4.23 (± 0.359) | | |
| Potassium, Week 48, n=265, 292 | 4.15 (± 0.271) | 4.16 (± 0.331) | | |
| Sodium, Baseline (Day 1), n=308, 308 | 139.0 (± 1.91) | 139.0 (± 1.76) | | |
| Sodium, Week 4, n=301, 303 | 139.3 (± 1.70) | 139.1 (± 1.87) | | |
| Sodium, Week 8, n=229, 303 | 139.1 (± 1.98) | 139.0 (± 1.80) | | |
| Sodium, Week 12, n=295, 299 | 139.2 (± 1.84) | 139.2 (± 1.85) | | |
| Sodium, Week 16, n=284, 298 | 139.1 (± 1.98) | 139.1 (± 1.96) | | |
| Sodium, Week 20, n=277, 302 | 139.2 (± 1.87) | 139.3 (± 1.81) | | |
| Sodium, Week 24, n=284, 299 | 139.3 (± 1.88) | 139.3 (± 1.96) | | |
| Sodium, Week 28, n=267, 296 | 139.5 (± 1.77) | 139.2 (± 2.01) | | |

| | | | | |
|------------------------------------|----------------|----------------|--|--|
| Sodium, Week 32, n=275, 294 | 139.3 (± 1.75) | 139.5 (± 1.84) | | |
| Sodium, Week 36, n=273, 292 | 139.4 (± 1.79) | 139.5 (± 2.15) | | |
| Sodium, Week 40, n=270, 293 | 139.4 (± 1.93) | 139.5 (± 1.97) | | |
| Sodium, Week 44, n=275, 293 | 139.4 (± 1.80) | 139.5 (± 1.93) | | |
| Sodium, Week 48, n=265, 292 | 139.4 (± 1.94) | 139.4 (± 1.83) | | |
| Urea, Baseline (Day 1), n=308, 308 | 5.23 (± 1.546) | 5.22 (± 1.632) | | |
| Urea, Week 4, n=301, 303 | 5.24 (± 1.495) | 5.28 (± 1.549) | | |
| Urea, Week 8, n=229, 303 | 5.32 (± 1.640) | 5.22 (± 1.529) | | |
| Urea, Week 12, n=295, 299 | 5.38 (± 1.612) | 5.30 (± 1.649) | | |
| Urea, Week 16, n=284, 298 | 5.30 (± 1.662) | 5.41 (± 1.659) | | |
| Urea, Week 20, n=277, 302 | 5.37 (± 1.631) | 5.33 (± 1.662) | | |
| Urea, Week 24, n=284, 299 | 5.49 (± 1.749) | 5.36 (± 1.639) | | |
| Urea, Week 28, n=267, 296 | 5.39 (± 1.756) | 5.24 (± 1.527) | | |
| Urea, Week 32, n=275, 294 | 5.44 (± 1.624) | 5.29 (± 1.599) | | |
| Urea, Week 36, n=273, 292 | 5.26 (± 1.664) | 5.20 (± 1.485) | | |
| Urea, Week 40, n=270, 293 | 5.47 (± 1.593) | 5.30 (± 1.537) | | |
| Urea, Week 44, n=275, 293 | 5.37 (± 1.531) | 5.26 (± 1.524) | | |
| Urea, Week 48, n=265, 292 | 5.48 (± 1.648) | 5.21 (± 1.437) | | |

Notes:

[51] - Safety Population

[52] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[53] | 308 ^[54] | | |
| Units: Units per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline, n=308, 308 | 30.5 (± 22.88) | 30.8 (± 19.12) | | |
| Week 4, n=301, 303 | 35.3 (± 52.73) | 32.3 (± 23.30) | | |
| Week 8, n=227, 303 | 30.6 (± 22.70) | 31.9 (± 20.71) | | |
| Week 12, n=294, 297 | 33.2 (± 27.92) | 30.0 (± 18.06) | | |
| Week 16, n=285, 299 | 33.8 (± 30.49) | 33.9 (± 34.69) | | |
| Week 20, n=278, 302 | 31.0 (± 21.73) | 31.6 (± 28.88) | | |

| | | | | |
|---------------------|----------------|----------------|--|--|
| Week 24, n=283, 299 | 33.1 (± 24.09) | 33.8 (± 29.69) | | |
| Week 28, n=267, 297 | 32.9 (± 27.42) | 33.1 (± 19.69) | | |
| Week 32, n=274, 294 | 35.7 (± 60.63) | 33.8 (± 21.64) | | |
| Week 36, n=273, 292 | 36.2 (± 51.58) | 31.6 (± 18.46) | | |
| Week 40, n=269, 293 | 35.7 (± 36.06) | 31.4 (± 15.80) | | |
| Week 44, n=274, 293 | 33.3 (± 26.29) | 33.3 (± 20.44) | | |
| Week 48, n=264, 290 | 34.3 (± 30.97) | 32.4 (± 20.40) | | |

Notes:

[53] - Safety Population

[54] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[55] | 308 ^[56] | | |
| Units: Milliliter per minute per 1.73meter ² | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline, n=308, 308 | 100.5 (± 18.30) | 101.1 (± 17.72) | | |
| Week 4, n=301, 301 | 98.7 (± 17.26) | 98.9 (± 17.93) | | |
| Week 8, n=227, 303 | 100.1 (± 17.19) | 99.5 (± 17.59) | | |
| Week 12, n=295, 297 | 100.9 (± 17.72) | 99.2 (± 18.34) | | |
| Week 16, n=284, 297 | 100.5 (± 17.26) | 99.0 (± 18.32) | | |
| Week 20, n=277, 302 | 99.4 (± 17.37) | 98.7 (± 17.73) | | |
| Week 24, n=283, 298 | 98.9 (± 17.04) | 98.9 (± 17.44) | | |
| Week 28, n=267, 296 | 98.5 (± 17.66) | 99.0 (± 17.33) | | |
| Week 32, n=274, 294 | 99.1 (± 16.89) | 98.4 (± 17.54) | | |
| Week 36, n=273, 292 | 99.0 (± 17.19) | 98.6 (± 16.85) | | |
| Week 40, n=268, 293 | 98.5 (± 17.32) | 98.5 (± 17.37) | | |
| Week 44, n=274, 293 | 98.2 (± 16.96) | 99.0 (± 17.39) | | |
| Week 48, n=264, 291 | 97.6 (± 16.97) | 99.3 (± 17.09) | | |

Notes:

[55] - Safety Population

[56] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|-----------------|--|
| End point title | Number of participants with abnormal urinalysis parameters over time including Week 48 |
|-----------------|--|

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[57] | 308 ^[58] | | |
| Units: Participants | | | | |
| Urine bilirubin,Baseline (Day 1),Trace, n=303, 301 | 0 | 0 | | |
| Urine bilirubin, Baseline (Day 1), 1+, n=303, 301 | 6 | 7 | | |
| Urine bilirubin, Baseline (Day 1), 2+, n=303, 301 | 0 | 0 | | |
| Urine bilirubin, Baseline (Day 1), 3+, n=303, 301 | 0 | 0 | | |
| Urine glucose, Baseline (Day 1), Trace, n=303, 301 | 1 | 1 | | |
| Urine glucose, Baseline (Day 1), 1+, n=303, 301 | 0 | 1 | | |
| Urine glucose, Baseline (Day 1), 2+, n=303, 301 | 0 | 0 | | |
| Urine glucose, Baseline (Day 1), 3+, n=303, 301 | 0 | 1 | | |
| Urine ketones, Baseline (Day 1), Trace, n=303, 301 | 16 | 17 | | |
| Urine ketones, Baseline (Day 1), 1+, n=303, 301 | 4 | 0 | | |
| Urine ketones, Baseline (Day 1), 2+, n=303, 301 | 2 | 1 | | |
| Urine ketones, Baseline (Day 1), 3+, n=303, 301 | 0 | 0 | | |

| | | | | |
|--|----|----|--|--|
| Urine leukocyte esterase,Baseline,Trace,n=303,301 | 25 | 18 | | |
| Urine leukocyte esterase, Baseline, 1+, n=303, 301 | 14 | 16 | | |
| Urine leukocyte esterase, Baseline, 2+, n=303, 301 | 14 | 8 | | |
| Urine leukocyte esterase, Baseline, 3+, n=303, 301 | 5 | 5 | | |
| Urine nitrite, Baseline, positive, n=303, 301 | 11 | 11 | | |
| Urine occult blood, Baseline, Trace, n=303, 301 | 19 | 12 | | |
| Urine occult blood, Baseline, 1+, n=303, 301 | 8 | 9 | | |
| Urine occult blood, Baseline, 2+, n=303, 301 | 7 | 5 | | |
| Urine occult blood, Baseline, 3+, n=303, 301 | 5 | 3 | | |
| Urine protein, Baseline, Trace, n=303, 301 | 14 | 20 | | |
| Urine protein, Baseline, 1+, n=303, 301 | 6 | 12 | | |
| Urine protein, Baseline, 2+, n=303, 301 | 0 | 1 | | |
| Urine protein, Baseline, 3+, n=303, 301 | 0 | 0 | | |
| Urine protein, Baseline, 4+, n=303, 301 | 0 | 0 | | |
| Urine bilirubin, Week 4, Trace, n=303, 302 | 0 | 0 | | |
| Urine bilirubin, Week 4, 1+, n=303, 302 | 9 | 5 | | |
| Urine bilirubin, Week 4, 2+, n=303, 302 | 0 | 0 | | |
| Urine bilirubin, Week 4, 3+, n=303, 302 | 0 | 0 | | |
| Urine glucose, Week 4, Trace, n=303, 302 | 3 | 2 | | |
| Urine glucose, Week 4, 1+, n=303, 302 | 1 | 2 | | |
| Urine glucose, Week 4, 2+, n=303, 302 | 2 | 0 | | |
| Urine glucose, Week 4, 3+, n=303, 302 | 0 | 1 | | |
| Urine ketones, Week 4, Trace, n=303, 302 | 9 | 15 | | |
| Urine ketones, Week 4, 1+, n=303, 302 | 0 | 2 | | |
| Urine ketones, Week 4, 2+, n=303, 302 | 1 | 1 | | |
| Urine ketones, Week 4, 3+, n=303, 302 | 0 | 0 | | |
| Urine leukocyte esterase, Week 4, Trace,n=303, 302 | 25 | 29 | | |
| Urine leukocyte esterase, Week 4, 1+, n=303, 302 | 14 | 15 | | |
| Urine leukocyte esterase, Week 4, 2+, n=303, 302 | 14 | 9 | | |
| Urine leukocyte esterase, Week 4, 3+, n=303, 302 | 3 | 4 | | |
| Urine nitrite, Week 4, positive, n=303, 302 | 10 | 12 | | |
| Urine occult blood, Week 4, Trace, n=303, 302 | 15 | 18 | | |
| Urine occult blood, Week 4, 1+, n=303, 302 | 9 | 10 | | |
| Urine occult blood, Week 4, 2+, n=303, 302 | 5 | 5 | | |
| Urine occult blood, Week 4, 3+, n=303, 302 | 4 | 3 | | |
| Urine protein, Week 4, Trace, n=303, 302 | 10 | 13 | | |

| | | | | |
|--|----|----|--|--|
| Urine protein, Week 4, 1+, n=303, 302 | 8 | 7 | | |
| Urine protein, Week 4, 2+, n=303, 302 | 2 | 4 | | |
| Urine protein, Week 4, 3+, n=303, 302 | 0 | 0 | | |
| Urine protein, Week 4, 4+, n=303, 302 | 0 | 0 | | |
| Urine bilirubin, Week 24, Trace, n=279, 298 | 0 | 0 | | |
| Urine bilirubin, Week 24, 1+, n=279, 298 | 10 | 13 | | |
| Urine bilirubin, Week 24, 2+, n=279, 298 | 0 | 0 | | |
| Urine bilirubin, Week 24, 3+, n=279, 298 | 0 | 0 | | |
| Urine glucose, Week 24, Trace, n=279, 298 | 0 | 1 | | |
| Urine glucose, Week 24, 1+, n=279, 298 | 2 | 0 | | |
| Urine glucose, Week 24, 2+, n=279, 298 | 0 | 1 | | |
| Urine glucose, Week 24, 3+, n=279, 298 | 1 | 1 | | |
| Urine ketones, Week 24, Trace, n=279, 298 | 16 | 13 | | |
| Urine ketones, Week 24, 1+, n=279, 298 | 1 | 1 | | |
| Urine ketones, Week 24, 2+, n=279, 298 | 0 | 0 | | |
| Urine ketones, Week 24, 3+, n=279, 298 | 0 | 0 | | |
| Urine leukocyte esterase, Week 24, Trace, n=279, 298 | 22 | 17 | | |
| Urine leukocyte esterase, Week 24, 1+, n=279, 298 | 14 | 14 | | |
| Urine leukocyte esterase, Week 24, 2+, n=279, 298 | 6 | 14 | | |
| Urine leukocyte esterase, Week 24, 3+, n=279, 298 | 3 | 7 | | |
| Urine nitrite, Week 24, positive, n=279, 298 | 9 | 10 | | |
| Urine occult blood, Week 24, Trace, n=279, 298 | 13 | 10 | | |
| Urine occult blood, Week 24, 1+, n=279, 298 | 5 | 6 | | |
| Urine occult blood, Week 24, 2+, n=279, 298 | 6 | 4 | | |
| Urine occult blood, Week 24, 3+, n=279, 298 | 0 | 6 | | |
| Urine protein, Week 24, Trace, n=279, 298 | 10 | 21 | | |
| Urine protein, Week 24, 1+, n=279, 298 | 4 | 12 | | |
| Urine protein, Week 24, 2+, n=279, 298 | 1 | 3 | | |
| Urine protein, Week 24, 3+, n=279, 298 | 0 | 0 | | |
| Urine protein, Week 24, 4+, n=279, 298 | 0 | 0 | | |
| Urine bilirubin, Week 48, Trace, n=279, 290 | 0 | 0 | | |
| Urine bilirubin, Week 48, 1+, n=279, 290 | 9 | 8 | | |
| Urine bilirubin, Week 48, 2+, n=279, 290 | 1 | 0 | | |
| Urine bilirubin, Week 48, 3+, n=279, 290 | 0 | 0 | | |

| | | | | |
|--|----|----|--|--|
| Urine glucose, Week 48, Trace, n=279, 290 | 0 | 1 | | |
| Urine glucose, Week 48, 1+, n=279, 290 | 0 | 2 | | |
| Urine glucose, Week 48, 2+, n=279, 290 | 1 | 0 | | |
| Urine glucose, Week 48, 3+, n=279, 290 | 0 | 2 | | |
| Urine ketones, Week 48, Trace, n=279, 290 | 13 | 9 | | |
| Urine ketones, Week 48, 1+, n=279, 290 | 0 | 0 | | |
| Urine ketones, Week 48, 2+, n=279, 290 | 0 | 0 | | |
| Urine ketones, Week 48, 3+, n=279, 290 | 0 | 0 | | |
| Urine leukocyte esterase, Week 48, Trace, n=279, 290 | 24 | 27 | | |
| Urine leukocyte esterase, Week 48, 1+, n=279, 290 | 13 | 15 | | |
| Urine leukocyte esterase, Week 48, 2+, n=279, 290 | 7 | 7 | | |
| Urine leukocyte esterase, Week 48, 3+, n=279, 290 | 5 | 6 | | |
| Urine nitrite, Week 48, positive, n=279, 290 | 10 | 6 | | |
| Urine occult blood, Week 48, Trace, n=279, 290 | 11 | 12 | | |
| Urine occult blood, Week 48, 1+, n=279, 290 | 5 | 5 | | |
| Urine occult blood, Week 48, 2+, n=279, 290 | 4 | 4 | | |
| Urine occult blood, Week 48, 3+, n=279, 290 | 6 | 0 | | |
| Urine protein, Week 48, Trace, n=279, 290 | 10 | 15 | | |
| Urine protein, Week 48, 1+, n=279, 290 | 4 | 6 | | |
| Urine protein, Week 48, 2+, n=279, 290 | 3 | 3 | | |
| Urine protein, Week 48, 3+, n=279, 290 | 0 | 0 | | |
| Urine protein, Week 48, 4+, n=279, 290 | 0 | 1 | | |

Notes:

[57] - Safety Population

[58] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[59] | 308 ^[60] | | |
| Units: Participants | | | | |
| Baseline, pH=5, n=303, 301 | 44 | 42 | | |
| Baseline, pH=5.5, n=303, 301 | 78 | 80 | | |
| Baseline, pH=6, n=303, 301 | 85 | 72 | | |
| Baseline, pH=6.5, n=303, 301 | 47 | 45 | | |
| Baseline, pH=7, n=303, 301 | 32 | 34 | | |
| Baseline, pH=7.5, n=303, 301 | 12 | 19 | | |
| Baseline, pH=8, n=303, 301 | 3 | 7 | | |
| Baseline, pH=8.5, n=303, 301 | 0 | 1 | | |
| Baseline, pH>9.0, n=303, 301 | 2 | 1 | | |
| Week 4, pH=5, n=303, 302 | 41 | 53 | | |
| Week 4, pH=5.5, n=303, 302 | 78 | 93 | | |
| Week 4, pH=6, n=303, 302 | 73 | 67 | | |
| Week 4, pH=6.5, n=303, 302 | 49 | 41 | | |
| Week 4, pH=7, n=303, 302 | 38 | 28 | | |
| Week 4, pH=7.5, n=303, 302 | 12 | 14 | | |
| Week 4, pH=8, n=303, 302 | 8 | 3 | | |
| Week 4, pH=8.5, n=303, 302 | 3 | 2 | | |
| Week 4, pH>9.0, n=303, 302 | 1 | 1 | | |
| Week 24, pH=5, n=279, 298 | 23 | 26 | | |
| Week 24, pH=5.5, n=279, 298 | 85 | 96 | | |
| Week 24, pH=6, n=279, 298 | 66 | 67 | | |
| Week 24, pH=6.5, n=279, 298 | 44 | 52 | | |
| Week 24, pH=7, n=279, 298 | 32 | 31 | | |
| Week 24, pH=7.5, n=279, 298 | 16 | 15 | | |
| Week 24, pH=8, n=279, 298 | 7 | 8 | | |
| Week 24, pH=8.5, n=279, 298 | 2 | 2 | | |
| Week 24, pH>9.0, n=279, 298 | 4 | 1 | | |
| Week 48, pH=5, n=279, 290 | 45 | 43 | | |
| Week 48, pH=5.5, n=279, 290 | 69 | 83 | | |
| Week 48, pH=6, n=279, 290 | 61 | 58 | | |
| Week 48, pH=6.5, n=279, 290 | 47 | 48 | | |
| Week 48, pH=7, n=279, 290 | 31 | 30 | | |
| Week 48, pH=7.5, n=279, 290 | 17 | 17 | | |
| Week 48, pH=8, n=279, 290 | 6 | 5 | | |
| Week 48, pH=8.5, n=279, 290 | 0 | 4 | | |
| Week 48, pH>9.0, n=279, 290 | 3 | 2 | | |

Notes:

[59] - Safety Population

[60] - Safety Population

Statistical analyses

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

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

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[61] | 308 ^[62] | | |
| Units: International units per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| ALT, Week 4, n=301, 303 | 0.8 (± 13.98) | 0.1 (± 9.65) | | |
| ALT, Week 8, n=229, 303 | 0.7 (± 15.35) | 1.6 (± 29.98) | | |
| ALT, Week 12, n=295, 299 | 5.2 (± 113.34) | 0.4 (± 11.60) | | |
| ALT, Week 16, n=284, 298 | -0.1 (± 21.80) | -0.6 (± 10.14) | | |
| ALT, Week 20, n=277, 302 | -0.8 (± 22.62) | -1.1 (± 10.86) | | |
| ALT, Week 24, n=284, 299 | 2.2 (± 61.65) | -0.6 (± 10.57) | | |
| ALT, Week 28, n=267, 296 | -2.7 (± 11.14) | -0.2 (± 12.52) | | |
| ALT, Week 32, n=275, 294 | -1.9 (± 14.44) | -0.5 (± 11.49) | | |
| ALT, Week 36, n=273, 292 | -0.8 (± 23.51) | 0.1 (± 10.95) | | |
| ALT, Week 40, n=270, 293 | 0.6 (± 36.29) | -0.2 (± 11.82) | | |
| ALT, Week 44, n=275, 293 | -2.2 (± 13.97) | -0.2 (± 12.37) | | |
| ALT, Week 48, n=265, 292 | -1.9 (± 13.43) | -0.6 (± 10.50) | | |
| ALP, Week 4, n=301, 303 | -6.0 (± 12.74) | -2.2 (± 8.85) | | |
| ALP, Week 8, n=229, 303 | -6.7 (± 16.59) | 1.1 (± 20.99) | | |
| ALP, Week 12, n=295, 299 | -8.0 (± 20.87) | 0.9 (± 14.45) | | |
| ALP, Week 16, n=284, 298 | -9.7 (± 19.47) | -0.5 (± 10.35) | | |
| ALP, Week 20, n=277, 302 | -9.2 (± 19.05) | -1.0 (± 11.65) | | |
| ALP, Week 24, n=284, 299 | -9.0 (± 19.02) | -0.1 (± 10.67) | | |
| ALP, Week 28, n=267, 296 | -10.1 (± 19.08) | -0.2 (± 11.44) | | |
| ALP, Week 32, n=275, 294 | -9.9 (± 19.10) | -1.7 (± 11.29) | | |
| ALP, Week 36, n=273, 292 | -10.5 (± 20.41) | -1.1 (± 11.44) | | |
| ALP, Week 40, n=270, 293 | -10.4 (± 20.71) | -1.1 (± 11.34) | | |
| ALP, Week 44, n=275, 293 | -11.4 (± 20.64) | -0.7 (± 12.02) | | |
| ALP, Week 48, n=265, 292 | -10.9 (± 23.27) | -0.3 (± 12.51) | | |
| AST, Week 4, n=301, 303 | -0.3 (± 12.52) | 0.2 (± 10.02) | | |

| | | | | |
|--------------------------|------------------|------------------|--|--|
| AST, Week 8, n=229, 303 | 1.2 (± 19.73) | -0.1 (± 13.68) | | |
| AST, Week 12, n=295, 299 | 2.3 (± 65.03) | 0.6 (± 8.82) | | |
| AST, Week 16, n=284, 298 | 0.1 (± 18.49) | -0.1 (± 9.71) | | |
| AST, Week 20, n=277, 302 | -0.5 (± 17.02) | -0.6 (± 9.80) | | |
| AST, Week 24, n=284, 298 | 0.1 (± 24.12) | 0.0 (± 9.57) | | |
| AST, Week 28, n=267, 296 | -1.4 (± 8.77) | 0.3 (± 11.19) | | |
| AST, Week 32, n=275, 294 | -1.2 (± 16.08) | 0.6 (± 13.40) | | |
| AST, Week 36, n=273, 292 | -1.2 (± 12.95) | 0.1 (± 9.61) | | |
| AST, Week 40, n=270, 293 | -0.2 (± 17.27) | 0.0 (± 10.64) | | |
| AST, Week 44, n=275, 293 | -1.1 (± 16.51) | 0.1 (± 11.09) | | |
| AST, Week 48, n=265, 292 | -1.0 (± 12.79) | 0.7 (± 10.75) | | |
| CK, Week 4, n=301, 303 | -0.1 (± 548.15) | 30.8 (± 435.12) | | |
| CK, Week 8, n=229, 303 | 98.2 (± 1076.99) | -16.5 (± 344.96) | | |
| CK, Week 12, n=295, 299 | 6.0 (± 585.45) | 14.9 (± 288.85) | | |
| CK, Week 16, n=284, 298 | 54.2 (± 882.23) | 5.8 (± 411.52) | | |
| CK, Week 20, n=277, 302 | 31.2 (± 653.11) | -16.7 (± 363.30) | | |
| CK, Week 24, n=284, 299 | -9.2 (± 538.95) | -0.7 (± 353.99) | | |
| CK, Week 28, n=267, 296 | -1.9 (± 213.98) | 20.8 (± 538.83) | | |
| CK, Week 32, n=275, 294 | 13.3 (± 699.60) | 34.0 (± 597.29) | | |
| CK, Week 36, n=273, 292 | -18.2 (± 476.64) | -10.8 (± 358.72) | | |
| CK, Week 40, n=270, 293 | 39.7 (± 704.18) | -0.3 (± 373.96) | | |
| CK, Week 44, n=275, 293 | 47.4 (± 1185.55) | -10.9 (± 350.64) | | |
| CK, Week 48, n=265, 292 | -0.6 (± 528.71) | 18.1 (± 463.49) | | |

Notes:

[61] - Safety Population

[62] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-albumin. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[63] | 308 ^[64] | | |
| Units: Grams per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=301, 303 | -0.5 (± 2.60) | -0.5 (± 2.49) | | |
| Week 8, n=229, 303 | -0.3 (± 2.76) | -0.7 (± 2.70) | | |
| Week 12, n=295, 299 | -0.6 (± 2.72) | -0.4 (± 2.63) | | |
| Week 16, n=284, 298 | -0.6 (± 2.78) | -0.8 (± 2.70) | | |
| Week 20, n=277, 302 | -0.8 (± 2.78) | -0.8 (± 2.56) | | |
| Week 24, n=284, 299 | -0.7 (± 2.69) | -0.8 (± 2.59) | | |
| Week 28, n=267, 296 | -0.7 (± 2.60) | -1.0 (± 2.47) | | |
| Week 32, n=275, 294 | -0.6 (± 2.78) | -1.0 (± 2.56) | | |
| Week 36, n=273, 292 | -0.9 (± 2.71) | -0.9 (± 2.65) | | |
| Week 40, n=270, 293 | -0.5 (± 2.53) | -1.0 (± 2.61) | | |
| Week 44, n=275, 293 | -0.4 (± 2.58) | -0.8 (± 2.47) | | |
| Week 48, n=265, 292 | -0.4 (± 2.64) | -0.4 (± 2.55) | | |

Notes:

[63] - Safety Population

[64] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[65] | 308 ^[66] | | |
| Units: Micromoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Bilirubin, Week 4, n=301, 303 | -0.8 (± 9.87) | -0.3 (± 4.17) | | |

| | | | | |
|---------------------------------------|-----------------|----------------|--|--|
| Bilirubin, Week 8, n=229, 303 | -0.1 (± 6.92) | 0.1 (± 7.66) | | |
| Bilirubin, Week 12, n=295, 299 | -0.6 (± 10.23) | 0.1 (± 4.56) | | |
| Bilirubin, Week 16, n=284, 298 | 0.2 (± 14.00) | -0.2 (± 4.12) | | |
| Bilirubin, Week 20, n=277, 302 | -0.2 (± 10.04) | 0.0 (± 6.10) | | |
| Bilirubin, Week 24, n=284, 298 | -0.6 (± 9.90) | 0.2 (± 5.90) | | |
| Bilirubin, Week 28, n=267, 296 | 0.0 (± 10.46) | -0.1 (± 4.76) | | |
| Bilirubin, Week 32, n=275, 294 | -0.1 (± 10.36) | 0.0 (± 4.94) | | |
| Bilirubin, Week 36, n=273, 292 | -0.6 (± 10.39) | 0.1 (± 4.55) | | |
| Bilirubin, Week 40, n=270, 293 | -0.3 (± 10.61) | 0.2 (± 6.28) | | |
| Bilirubin, Week 44, n=275, 293 | -0.4 (± 10.11) | 0.4 (± 5.24) | | |
| Bilirubin, Week 48, n=265, 292 | -0.3 (± 10.57) | 0.2 (± 3.91) | | |
| Direct bilirubin, Week 4, n=301, 303 | -0.1 (± 1.48) | 0.1 (± 1.20) | | |
| Direct bilirubin, Week 8, n=229, 303 | -0.1 (± 1.42) | 0.2 (± 3.96) | | |
| Direct bilirubin, Week 12, n=295, 299 | -0.2 (± 1.61) | 0.1 (± 1.21) | | |
| Direct bilirubin, Week 16, n=284, 298 | 0.1 (± 5.02) | -0.1 (± 1.12) | | |
| Direct bilirubin, Week 20, n=277, 302 | -0.3 (± 1.52) | -0.2 (± 1.29) | | |
| Direct bilirubin, Week 24, n=284, 298 | -0.2 (± 1.55) | -0.1 (± 1.24) | | |
| Direct bilirubin, Week 28, n=267, 296 | -0.3 (± 1.55) | -0.2 (± 1.29) | | |
| Direct bilirubin, Week 32, n=275, 294 | -0.3 (± 1.61) | -0.2 (± 1.24) | | |
| Direct bilirubin, Week 36, n=273, 292 | -0.3 (± 1.70) | -0.1 (± 1.20) | | |
| Direct bilirubin, Week 40, n=270, 293 | -0.3 (± 1.68) | -0.2 (± 1.18) | | |
| Direct bilirubin, Week 44, n=275, 293 | -0.2 (± 1.55) | -0.1 (± 1.19) | | |
| Direct bilirubin, Week 48, n=265, 292 | -0.2 (± 1.54) | 0.0 (± 1.23) | | |
| Creatinine, Week 4, n=301, 301 | 1.15 (± 8.205) | 1.80 (± 8.022) | | |
| Creatinine, Week 8, n=229, 303 | -0.66 (± 9.042) | 1.23 (± 7.560) | | |
| Creatinine, Week 12, n=295, 299 | -0.38 (± 9.380) | 1.71 (± 7.638) | | |
| Creatinine, Week 16, n=284, 298 | -0.60 (± 9.225) | 1.62 (± 8.169) | | |
| Creatinine, Week 20, n=277, 302 | 0.53 (± 9.390) | 1.80 (± 8.454) | | |
| Creatinine, Week 24, n=284, 298 | 0.90 (± 12.494) | 1.36 (± 8.038) | | |
| Creatinine, Week 28, n=267, 296 | 1.14 (± 10.998) | 1.59 (± 8.303) | | |
| Creatinine, Week 32, n=275, 294 | 0.33 (± 10.102) | 1.95 (± 8.331) | | |
| Creatinine, Week 36, n=273, 292 | 0.34 (± 10.585) | 1.62 (± 7.891) | | |
| Creatinine, Week 40, n=270, 293 | 0.88 (± 9.986) | 1.64 (± 8.318) | | |
| Creatinine, Week 44, n=275, 293 | 1.03 (± 11.253) | 1.40 (± 8.008) | | |
| Creatinine, Week 48, n=265, 292 | 1.59 (± 11.253) | 0.82 (± 7.846) | | |

Notes:

[65] - Safety Population

[66] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|-----------------|---|
| End point title | Change from Baseline values for clinical chemistry parameters |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters which includes total CO₂, chloride, glucose, phosphate, potassium, sodium and urea. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type

Secondary

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[67] | 308 ^[68] | | |
| Units: Millimoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| CO ₂ , Week 4, n=301, 303 | 1.0 (± 2.53) | 0.7 (± 2.21) | | |
| CO ₂ , Week 8, n=229, 303 | 0.4 (± 2.31) | 0.6 (± 2.52) | | |
| CO ₂ , Week 12, n=295, 299 | 0.5 (± 2.42) | 0.3 (± 2.39) | | |
| CO ₂ , Week 16, n=284, 298 | 0.3 (± 2.42) | 0.5 (± 2.41) | | |
| CO ₂ , Week 20, n=277, 302 | 0.2 (± 2.26) | 0.3 (± 2.31) | | |
| CO ₂ , Week 24, n=284, 298 | 0.2 (± 2.46) | 0.2 (± 2.44) | | |
| CO ₂ , Week 28, n=267, 296 | 0.1 (± 2.47) | 0.1 (± 2.39) | | |
| CO ₂ , Week 32, n=275, 294 | 0.0 (± 2.37) | 0.2 (± 2.31) | | |
| CO ₂ , Week 36, n=273, 292 | 0.2 (± 2.37) | 0.3 (± 2.39) | | |
| CO ₂ , Week 40, n=270, 293 | 0.5 (± 2.49) | 0.4 (± 2.29) | | |
| CO ₂ , Week 44, n=275, 293 | 0.5 (± 2.34) | 0.5 (± 2.19) | | |
| CO ₂ , Week 48, n=265, 292 | 0.1 (± 2.41) | 0.2 (± 2.31) | | |
| Chloride, Week 4, n=301, 303 | 0.4 (± 2.05) | 0.5 (± 2.13) | | |
| Chloride, Week 8, n=229, 303 | 0.3 (± 2.12) | 0.5 (± 2.19) | | |
| Chloride, Week 12, n=295, 299 | 0.4 (± 2.30) | 0.5 (± 2.25) | | |
| Chloride, Week 16, n=284, 298 | 0.6 (± 2.41) | 0.8 (± 2.25) | | |
| Chloride, Week 20, n=277, 302 | 0.8 (± 2.32) | 0.8 (± 2.38) | | |
| Chloride, Week 24, n=284, 299 | 0.6 (± 2.48) | 0.9 (± 2.26) | | |
| Chloride, Week 28, n=267, 296 | 0.9 (± 2.21) | 1.0 (± 2.55) | | |
| Chloride, Week 32, n=275, 294 | 0.8 (± 2.41) | 0.9 (± 2.33) | | |
| Chloride, Week 36, n=273, 292 | 0.9 (± 2.18) | 0.9 (± 2.48) | | |
| Chloride, Week 40, n=270, 293 | 0.8 (± 2.24) | 0.8 (± 2.76) | | |
| Chloride, Week 44, n=275, 293 | 0.7 (± 2.20) | 0.8 (± 2.28) | | |
| Chloride, Week 48, n=265, 292 | 0.5 (± 2.36) | 0.3 (± 2.38) | | |
| Glucose, Week 4, n=218, 226 | 0.17 (± 0.721) | 0.21 (± 0.900) | | |
| Glucose, Week 8, n=151, 213 | 0.22 (± 0.841) | 0.22 (± 0.832) | | |
| Glucose, Week 12, n=204, 216 | 0.19 (± 0.855) | 0.19 (± 0.974) | | |
| Glucose, Week 16, n=207, 211 | 0.23 (± 1.050) | 0.27 (± 1.084) | | |
| Glucose, Week 20, n=192, 216 | 0.19 (± 0.712) | 0.19 (± 0.961) | | |
| Glucose, Week 24, n=212, 224 | 0.23 (± 0.710) | 0.16 (± 0.881) | | |
| Glucose, Week 28, n=188, 225 | 0.17 (± 0.793) | 0.28 (± 0.903) | | |
| Glucose, Week 32, n=192, 213 | 0.35 (± 0.956) | 0.27 (± 0.939) | | |
| Glucose, Week 36, n=190, 215 | 0.18 (± 0.803) | 0.26 (± 1.070) | | |

| | | | | |
|--------------------------------|------------------|-------------------|--|--|
| Glucose, Week 40, n=193, 213 | 0.27 (± 0.833) | 0.25 (± 0.891) | | |
| Glucose, Week 44, n=193, 213 | 0.23 (± 0.895) | 0.27 (± 0.898) | | |
| Glucose, Week 48, n=238, 274 | 0.04 (± 0.693) | 0.02 (± 0.924) | | |
| Phosphate, Week 4, n=301, 303 | 0.066 (± 0.1666) | 0.015 (± 0.1595) | | |
| Phosphate, Week 8, n=229, 303 | 0.062 (± 0.1862) | -0.006 (± 0.1609) | | |
| Phosphate, Week 12, n=295, 299 | 0.041 (± 0.1978) | 0.013 (± 0.1742) | | |
| Phosphate, Week 16, n=284, 298 | 0.041 (± 0.2012) | 0.003 (± 0.1640) | | |
| Phosphate, Week 20, n=277, 302 | 0.035 (± 0.1871) | 0.010 (± 0.1839) | | |
| Phosphate, Week 24, n=284, 299 | 0.042 (± 0.1963) | 0.006 (± 0.1845) | | |
| Phosphate, Week 28, n=267, 296 | 0.037 (± 0.1822) | 0.004 (± 0.1823) | | |
| Phosphate, Week 32, n=275, 294 | 0.021 (± 0.1980) | 0.005 (± 0.1886) | | |
| Phosphate, Week 36, n=273, 292 | 0.011 (± 0.1846) | -0.002 (± 0.1855) | | |
| Phosphate, Week 40, n=270, 293 | 0.024 (± 0.2035) | -0.004 (± 0.1736) | | |
| Phosphate, Week 44, n=275, 293 | 0.027 (± 0.1982) | 0.004 (± 0.1811) | | |
| Phosphate, Week 48, n=265, 292 | 0.034 (± 0.2007) | 0.003 (± 0.1741) | | |
| Potassium, Week 4, n=301, 303 | 0.05 (± 0.342) | 0.11 (± 0.375) | | |
| Potassium, Week 8, n=229, 303 | 0.01 (± 0.311) | 0.06 (± 0.393) | | |
| Potassium, Week 12, n=295, 299 | 0.04 (± 0.341) | 0.08 (± 0.356) | | |
| Potassium, Week 16, n=284, 298 | 0.01 (± 0.341) | 0.06 (± 0.340) | | |
| Potassium, Week 20, n=277, 302 | 0.04 (± 0.345) | 0.05 (± 0.359) | | |
| Potassium, Week 24, n=284, 298 | 0.03 (± 0.325) | 0.07 (± 0.337) | | |
| Potassium, Week 28, n=267, 296 | 0.04 (± 0.380) | 0.07 (± 0.389) | | |
| Potassium, Week 32, n=275, 294 | 0.02 (± 0.390) | 0.05 (± 0.347) | | |
| Potassium, Week 36, n=273, 292 | 0.03 (± 0.356) | 0.07 (± 0.359) | | |
| Potassium, Week 40, n=270, 293 | 0.04 (± 0.344) | 0.07 (± 0.350) | | |
| Potassium, Week 44, n=275, 293 | 0.06 (± 0.344) | 0.07 (± 0.372) | | |
| Potassium, Week 48, n=265, 292 | -0.02 (± 0.299) | 0.00 (± 0.332) | | |
| Sodium, Week 4, n=301, 303 | 0.3 (± 1.84) | 0.1 (± 1.99) | | |
| Sodium, Week 8, n=229, 303 | 0.2 (± 1.99) | -0.1 (± 1.92) | | |
| Sodium, Week 12, n=295, 299 | 0.2 (± 2.07) | 0.2 (± 1.91) | | |
| Sodium, Week 16, n=284, 298 | 0.1 (± 2.18) | 0.1 (± 2.06) | | |
| Sodium, Week 20, n=277, 302 | 0.3 (± 2.10) | 0.3 (± 1.95) | | |
| Sodium, Week 24, n=284, 299 | 0.3 (± 2.07) | 0.2 (± 1.95) | | |
| Sodium, Week 28, n=267, 296 | 0.5 (± 2.11) | 0.2 (± 2.24) | | |
| Sodium, Week 32, n=275, 294 | 0.3 (± 2.05) | 0.4 (± 1.89) | | |
| Sodium, Week 36, n=273, 292 | 0.5 (± 2.01) | 0.5 (± 2.19) | | |
| Sodium, Week 40, n=270, 293 | 0.4 (± 2.02) | 0.5 (± 2.07) | | |
| Sodium, Week 44, n=275, 293 | 0.5 (± 2.03) | 0.5 (± 2.05) | | |
| Sodium, Week 48, n=265, 292 | 0.4 (± 2.20) | 0.3 (± 1.95) | | |
| Urea, Week 4, n=301, 303 | 0.01 (± 1.369) | 0.08 (± 1.334) | | |
| Urea, Week 8, n=229, 303 | 0.07 (± 1.453) | 0.00 (± 1.363) | | |
| Urea, Week 12, n=295, 299 | 0.15 (± 1.409) | 0.09 (± 1.381) | | |
| Urea, Week 16, n=284, 298 | 0.08 (± 1.387) | 0.19 (± 1.496) | | |

| | | | | |
|---------------------------|----------------|-----------------|--|--|
| Urea, Week 20, n=277, 302 | 0.15 (± 1.399) | 0.11 (± 1.461) | | |
| Urea, Week 24, n=284, 299 | 0.25 (± 1.420) | 0.15 (± 1.311) | | |
| Urea, Week 28, n=267, 296 | 0.15 (± 1.524) | 0.00 (± 1.439) | | |
| Urea, Week 32, n=275, 294 | 0.20 (± 1.511) | 0.06 (± 1.415) | | |
| Urea, Week 36, n=273, 292 | 0.06 (± 1.420) | -0.02 (± 1.386) | | |
| Urea, Week 40, n=270, 293 | 0.19 (± 1.400) | 0.09 (± 1.452) | | |
| Urea, Week 44, n=275, 293 | 0.13 (± 1.426) | 0.02 (± 1.467) | | |
| Urea, Week 48, n=265, 292 | 0.24 (± 1.465) | -0.01 (± 1.312) | | |

Notes:

[67] - Safety Population

[68] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for fasting lipid panel over time including Week 48

| | |
|-----------------|---|
| End point title | Change from Baseline values for fasting lipid panel over time including Week 48 |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of fasting lipid parameters- total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at specified data points were analyzed (represented by n=X in category titles)

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

End point timeframe:

Baseline (Day 1) and at Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[69] | 308 ^[70] | | |
| Units: Millimoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Total cholesterol, Week 48, n=231, 242 | 0.08 (± 0.688) | -0.04 (± 0.665) | | |
| HDL cholesterol, Week 48, n=231, 242 | 0.040 (± 0.2702) | 0.002 (± 0.2682) | | |
| LDL cholesterol, Week 48, n=224, 238 | 0.098 (± 0.6105) | -0.017 (± 0.5314) | | |
| Triglycerides, Week 48, n=231, 242 | -0.159 (± 0.8670) | -0.033 (± 0.7844) | | |

Notes:

[69] - Safety Population

[70] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-lipase. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[71] | 308 ^[72] | | |
| Units: Units per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=301, 303 | 5.2 (± 41.42) | 1.5 (± 23.88) | | |
| Week 8, n=227, 303 | 1.2 (± 19.31) | 1.0 (± 17.96) | | |
| Week 12, n=294, 297 | 2.7 (± 25.12) | -0.8 (± 18.59) | | |
| Week 16, n=285, 299 | 2.6 (± 24.79) | 3.5 (± 31.03) | | |
| Week 20, n=278, 302 | 0.9 (± 15.65) | 0.8 (± 28.95) | | |
| Week 24, n=283, 299 | 2.1 (± 20.79) | 3.0 (± 23.85) | | |
| Week 28, n=267, 297 | 2.2 (± 24.93) | 2.3 (± 18.96) | | |
| Week 32, n=274, 294 | 5.2 (± 57.44) | 3.1 (± 21.31) | | |
| Week 36, n=273, 292 | 5.1 (± 49.92) | 0.7 (± 17.39) | | |
| Week 40, n=269, 293 | 5.1 (± 33.58) | 0.5 (± 17.60) | | |
| Week 44, n=274, 293 | 2.0 (± 22.57) | 2.3 (± 21.13) | | |
| Week 48, n=264, 290 | 3.0 (± 28.26) | 1.5 (± 19.00) | | |

Notes:

[71] - Safety Population

[72] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter-creatinine clearance. GFR was estimated by the central laboratory using the CKD-EPI. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[73] | 308 ^[74] | | |
| Units: Milliliters per minute per 1.73meter ² | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=301, 301 | -1.8 (± 9.51) | -2.3 (± 9.18) | | |
| Week 8, n=227, 303 | 0.4 (± 9.88) | -1.5 (± 8.06) | | |
| Week 12, n=295, 297 | 0.3 (± 10.28) | -1.9 (± 8.02) | | |
| Week 16, n=284, 297 | 0.4 (± 10.63) | -1.9 (± 8.69) | | |
| Week 20, n=277, 302 | -1.0 (± 10.37) | -2.4 (± 8.55) | | |
| Week 24, n=283, 298 | -1.0 (± 10.52) | -2.3 (± 8.76) | | |
| Week 28, n=267, 296 | -1.8 (± 11.47) | -2.4 (± 8.93) | | |
| Week 32, n=274, 294 | -1.2 (± 11.11) | -3.0 (± 8.94) | | |
| Week 36, n=273, 292 | -1.2 (± 11.26) | -2.6 (± 8.52) | | |
| Week 40, n=268, 293 | -1.7 (± 10.70) | -2.7 (± 9.10) | | |
| Week 44, n=274, 293 | -2.1 (± 10.45) | -2.3 (± 8.74) | | |
| Week 48, n=264, 291 | -2.5 (± 11.80) | -1.9 (± 8.50) | | |

Notes:

[73] - Safety Population

[74] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Urine biomarker samples were collected for the analysis of urine albumin/creatinine ratio and urine protein/creatinine ratio. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[75] | 308 ^[76] | | |
| Units: Grams per mole | | | | |
| arithmetic mean (standard deviation) | | | | |

| | | | | |
|---|------------------|------------------|--|--|
| Urine albumin/creatinine ratio, Week 4, n=210, 221 | 0.32 (± 3.948) | 0.06 (± 6.383) | | |
| Urine albumin/creatinine ratio, Week 24, n=198, 208 | -0.08 (± 3.360) | -0.11 (± 8.552) | | |
| Urine albumin/creatinine ratio, Week 48, n=191, 197 | 0.15 (± 6.049) | -0.14 (± 5.286) | | |
| Urine protein/creatinine, Week 4, n=234, 236 | -0.66 (± 11.803) | 1.85 (± 31.997) | | |
| Urine protein/creatinine, Week 24, n=208, 232 | -2.49 (± 8.028) | 1.67 (± 20.505) | | |
| Urine protein/creatinine, Week 48, n=206, 225 | -1.72 (± 9.551) | 6.70 (± 112.353) | | |

Notes:

[75] - Safety Population

[76] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|---|---|
| End point title | Change from Baseline values in urine creatinine over time including Week 48 |
| End point description: | |
| Urine biomarker samples were collected for the analysis of urine creatinine. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles). | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Day 1) and at Weeks 4, 24 and 48 | |

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[77] | 308 ^[78] | | |
| Units: Micromoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=304, 302 | -543.9 (± 8693.94) | -305.5 (± 8787.62) | | |
| Week 24, n=282, 297 | -341.8 (± 9286.26) | -270.4 (± 8437.76) | | |
| Week 48, n=282, 291 | -342.9 (± 8965.01) | -521.6 (± 7873.28) | | |

Notes:

[77] - Safety Population

[78] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

Week 48

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

End point description:

Urine biomarker samples were collected for the analysis of urine phosphate. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[79] | 308 ^[80] | | |
| Units: Millimoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=302, 300 | -0.460 (± 15.2707) | 1.483 (± 15.0378) | | |
| Week 24, n=281, 294 | 0.286 (± 16.1887) | 0.640 (± 14.4201) | | |
| Week 48, n=280, 291 | -0.369 (± 14.2441) | 1.254 (± 15.6532) | | |

Notes:

[79] - Safety Population

[80] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Urine biomarker samples were collected for the analysis of urine retinol binding protein. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed.

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

End point timeframe:

Baseline (Day 1) and at Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|----------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 275 ^[81] | 284 ^[82] | | |
| Units: Nanomoles per liter | | | | |
| arithmetic mean (standard deviation) | -1.8913 (± 14.10125) | 1.4289 (± 15.70559) | | |

Notes:

[81] - Safety Population

[82] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Urine biomarker samples were collected for the analysis of urine specific gravity. Urine specific gravity is a measure of the concentration of solutes in the urine and provides information on the kidney's ability to concentrate urine. The dipstick test gives results in a semi-quantitative manner. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. The urine specific gravity was measured as the ratio of urine density compared with water density. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[83] | 308 ^[84] | | |
| Units: Ratio of urine density to water density | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=298, 295 | -0.0009 (± 0.00800) | -0.0000 (± 0.00785) | | |
| Week 24, n=274, 291 | -0.0008 (± 0.00784) | -0.0000 (± 0.00770) | | |
| Week 48, n=274, 283 | -0.0009 (± 0.00772) | -0.0002 (± 0.00768) | | |

Notes:

[83] - Safety Population

[84] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|-----------------|---|
| End point title | Change from Baseline values in urine pH over time including |
|-----------------|---|

End point description:

Urine samples were collected for analysis of urine pH. pH is calculated on a scale of 0 to 14, values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH of less than 7 is acidic and a pH of greater than 7 is basic. Normal urine has a slightly acidic pH (5.0-6.0). The dipstick test gives results in a semi-quantitative manner. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[85] | 308 ^[86] | | |
| Units: pH | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4, n=298, 295 | 0.08 (± 0.886) | -0.13 (± 0.935) | | |
| Week 24, n=274, 291 | 0.18 (± 1.021) | 0.01 (± 0.870) | | |
| Week 48, n=274, 283 | 0.09 (± 1.036) | -0.02 (± 0.951) | | |

Notes:

[85] - Safety population

[86] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment.

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

End point timeframe:

Up to Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[87] | 308 ^[88] | | |
| Units: Participants | 13 | 5 | | |

Notes:

[87] - Safety Population

[88] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Blood samples were collected at Baseline and at Week 48 to assess fasting lipids which included total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Percentage change from Baseline is calculated as: value at Week 48 minus Baseline value divided by Baseline value multiplied by 100. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

Baseline (Day 1) and at Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[89] | 308 ^[90] | | |
| Units: Percent change | | | | |
| arithmetic mean (standard deviation) | | | | |
| Cholesterol, Week 48, Overall, n=231, 242 | 3.25 (± 15.563) | 0.13 (± 13.379) | | |
| HDL cholesterol, Week 48, Overall, n=231, 242 | 5.059 (± 20.5368) | 2.132 (± 18.0473) | | |
| LDL cholesterol, Week 48, Overall, n=224, 238 | 6.762 (± 31.7209) | 1.029 (± 19.4719) | | |
| Triglycerides, Week 48, Overall, n=231, 242 | 0.708 (± 43.5160) | 8.203 (± 51.7632) | | |

Notes:

[89] - Safety Population

[90] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with phenotypic resistance through Week 48

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

End point description:

The CVF population comprised of ITT-E population meeting CVF criteria. Phenotypic Resistant data for drugs: CAB, dolutegravir (DTG), elvitegravir (EVG), raltegravir (RAL), delavirdine (DLV),

efavirenz(EFV),etravirine(ETR),nevirapine(NVP),RPV,lamivudine(3TC),abacavir(ABC),emtricitabine(FTC),tenofovir(TDF),zidovudine(ZDV),stavudine(d4T),didanosine(ddI),atazanavir(ATV),darunavir(DRV),fosamprenavir(FPV),indinavir(IDV),lopinavir(LPV),nelfinavir(NFV),ritonavir(RTV),saquinavir(SQV) and tipranavir(TPV) in participants meeting CVF criteria is presented. Phenotypic resistance, partially sensitive, and Sensitive were based on fold change(FC) value from Monogram: resistance(FC>clinical higher cutoff/biologic cutoff), partially sensitive(FC<=clinical higher cutoff and >clinical lower cutoff), sensitive(FC<=clinical lower cutoff/biologic cutoff). Only those participants with data available at specified data points were analyzed (represented by n=X in category titles)

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At the time of CVF | |

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|------------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3 ^[91] | 4 ^[92] | | |
| Units: Participants | | | | |
| INI, CAB, resistant, n=3, 4 | 1 | 0 | | |
| INI, CAB, sensitive, n=3, 4 | 2 | 4 | | |
| INI, DTG, resistant, n=3, 4 | 0 | 0 | | |
| INI, DTG, partially sensitive, n=3, 4 | 0 | 0 | | |
| INI, DTG, sensitive, n=3, 4 | 3 | 4 | | |
| INI, EVG, resistant, n=3, 4 | 1 | 0 | | |
| INI, EVG, sensitive, n=3, 4 | 2 | 4 | | |
| INI, RAL, resistant, n=3, 4 | 1 | 0 | | |
| INI, RAL, sensitive, n=3, 4 | 2 | 4 | | |
| NNRTI, DLV, resistant, n=3, 3 | 2 | 0 | | |
| NNRTI, DLV, sensitive, n=3, 3 | 1 | 3 | | |
| NNRTI, EFV, resistant, n=3, 3 | 2 | 0 | | |
| NNRTI, EFV, sensitive, n=3, 3 | 1 | 3 | | |
| NNRTI, ETR, resistant, n=3, 3 | 0 | 0 | | |
| NNRTI, ETR, partially sensitive, n=3, 3 | 2 | 0 | | |
| NNRTI, ETR, sensitive, n=3, 3 | 1 | 3 | | |
| NNRTI, NVP, resistant, n=3, 3 | 2 | 0 | | |
| NNRTI, NVP, sensitive, n=3, 3 | 1 | 3 | | |
| NNRTI, RPV, resistant, n=3, 3 | 3 | 0 | | |
| NNRTI, RPV, sensitive, n=3, 3 | 0 | 3 | | |
| NRTI, 3TC, resistant, n=3, 3 | 0 | 1 | | |
| NRTI, 3TC, sensitive, n=3, 3 | 3 | 2 | | |
| NRTI, ABC, resistant, n=3, 3 | 0 | 0 | | |
| NRTI, ABC, partially sensitive, n=3, 3 | 0 | 0 | | |
| NRTI, ABC, sensitive, n=3, 3 | 3 | 3 | | |
| NRTI, FTC, resistant, n=3, 3 | 0 | 1 | | |
| NRTI, FTC, sensitive, n=3, 3 | 3 | 2 | | |
| NRTI, TDF, resistant, n=3, 3 | 0 | 0 | | |
| NRTI, TDF, partially sensitive, n=3, 3 | 0 | 0 | | |
| NRTI, TDF, sensitive, n=3, 3 | 3 | 3 | | |
| NRTI, ZDV, resistant, n=3, 3 | 1 | 0 | | |
| NRTI, ZDV, sensitive, n=3, 3 | 2 | 3 | | |
| NRTI, d4T, resistant, n=3, 3 | 0 | 0 | | |
| NRTI, d4T, sensitive, n=3, 3 | 3 | 3 | | |

| | | | | |
|--|---|---|--|--|
| NRTI, ddI, resistant, n=3, 3 | 0 | 0 | | |
| NRTI, ddI, partially sensitive, n=3, 3 | 0 | 0 | | |
| NRTI, ddI, sensitive, n=3, 3 | 3 | 3 | | |
| PI, ATV, resistant, n=3, 3 | 0 | 0 | | |
| PI, ATV, sensitive, n=3, 3 | 3 | 3 | | |
| PI, DRV, resistant, n=3, 3 | 0 | 0 | | |
| PI, DRV, partially sensitive, n=3, 3 | 0 | 0 | | |
| PI, DRV, sensitive, n=3, 3 | 3 | 3 | | |
| PI, FPV, resistant, n=3, 3 | 0 | 0 | | |
| PI, FPV, partially sensitive, n=3, 3 | 0 | 0 | | |
| PI, FPV, sensitive, n=3, 3 | 3 | 3 | | |
| PI, IDV, resistant, n=3, 3 | 0 | 0 | | |
| PI, IDV, sensitive, n=3, 3 | 3 | 3 | | |
| PI, LPV, resistant, n=3, 3 | 0 | 0 | | |
| PI, LPV, partially sensitive, n=3, 3 | 0 | 0 | | |
| PI, LPV, sensitive, n=3, 3 | 3 | 3 | | |
| PI, NFV, resistant, n=3, 3 | 0 | 0 | | |
| PI, NFV, sensitive, n=3, 3 | 3 | 3 | | |
| PI, RTV, resistant, n=3, 3 | 0 | 0 | | |
| PI, RTV, sensitive, n=3, 3 | 3 | 3 | | |
| PI, SQV, resistant, n=3, 3 | 0 | 0 | | |
| PI, SQV, partially sensitive, n=3, 3 | 0 | 0 | | |
| PI, SQV, sensitive, n=3, 3 | 3 | 3 | | |
| PI, TPV, resistant, n=3, 3 | 0 | 0 | | |
| PI, TPV, partially sensitive, n=3, 3 | 0 | 0 | | |
| PI, TPV, sensitive, n=3, 3 | 3 | 3 | | |

Notes:

[91] - CVF Population

[92] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with genotypic resistance through Week 48

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

End point description:

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

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

End point timeframe:

At the time of CVF

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---------------------------------|------------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3 ^[93] | 4 ^[94] | | |
| Units: Participants | | | | |
| INI, DTG, resistant | 0 | 0 | | |
| INI, DTG, resistance possible | 0 | 0 | | |
| INI, DTG, sensitive | 3 | 4 | | |
| INI, EVG, resistant | 1 | 0 | | |
| INI, EVG, resistance possible | 0 | 0 | | |
| INI, EVG, sensitive | 2 | 4 | | |
| INI, RAL, resistant | 1 | 0 | | |
| INI, RAL, resistance possible | 0 | 0 | | |
| INI, RAL, sensitive | 2 | 4 | | |
| NNRTI, DLV, resistant | 0 | 0 | | |
| NNRTI, DLV, resistance possible | 0 | 0 | | |
| NNRTI, DLV, sensitive | 3 | 4 | | |
| NNRTI, EFV, resistant | 1 | 1 | | |
| NNRTI, EFV, resistance possible | 0 | 0 | | |
| NNRTI, EFV, sensitive | 2 | 3 | | |
| NNRTI, ETR, resistant | 0 | 0 | | |
| NNRTI, ETR, resistance possible | 2 | 0 | | |
| NNRTI, ETR, sensitive | 1 | 4 | | |
| NNRTI, NVP, resistant | 1 | 1 | | |
| NNRTI, NVP, resistance possible | 0 | 0 | | |
| NNRTI, NVP, sensitive | 2 | 3 | | |
| NNRTI, RPV, resistant | 3 | 1 | | |
| NNRTI, RPV, resistance possible | 0 | 0 | | |
| NNRTI, RPV, sensitive | 0 | 3 | | |
| NRTI, 3TC, resistant | 0 | 2 | | |
| NNRTI, 3TC, resistance possible | 0 | 0 | | |
| NRTI, 3TC, sensitive | 3 | 2 | | |
| NRTI, ABC, resistant | 0 | 0 | | |
| NRTI, ABC, resistance possible | 0 | 0 | | |
| NRTI, ABC, sensitive | 3 | 4 | | |
| NRTI, FTC, resistant | 0 | 2 | | |
| NRTI, FTC, resistance possible | 0 | 0 | | |
| NRTI, FTC, sensitive | 3 | 2 | | |
| NRTI, TDF, resistant | 0 | 0 | | |
| NRTI, TDF, resistance possible | 0 | 0 | | |
| NRTI, TDF, sensitive | 3 | 4 | | |
| NRTI, ZDV, resistant | 0 | 0 | | |
| NRTI, ZDV, resistance possible | 0 | 0 | | |
| NRTI, ZDV, sensitive | 3 | 4 | | |
| NRTI, d4T, resistant | 0 | 0 | | |
| NRTI, d4T, resistance possible | 0 | 0 | | |
| NRTI, d4T, sensitive | 3 | 4 | | |
| NRTI, ddI, resistant | 0 | 0 | | |
| NRTI, ddI, resistance possible | 0 | 2 | | |
| NRTI, ddI, sensitive | 3 | 2 | | |
| PI, ATV, resistant | 1 | 0 | | |
| PI, ATV, resistance possible | 0 | 0 | | |

| | | | | |
|--------------------------------|---|---|--|--|
| PI, ATV, sensitive | 2 | 4 | | |
| PI, ATV/r, resistant | 0 | 0 | | |
| PI, ATV/r, resistance possible | 1 | 0 | | |
| PI, ATV/r, sensitive | 2 | 4 | | |
| PI, DRV/r, resistant | 0 | 0 | | |
| PI, DRV/r, resistance possible | 0 | 0 | | |
| PI, DRV/r, sensitive | 3 | 4 | | |
| PI, FPV/r, resistant | 0 | 0 | | |
| PI, FPV/r, resistance possible | 0 | 0 | | |
| PI, FPV/r, sensitive | 3 | 4 | | |
| PI, IDV/r, resistant | 0 | 0 | | |
| PI, IDV/r, resistance possible | 0 | 0 | | |
| PI, IDV/r, sensitive | 3 | 4 | | |
| PI, LPV/r, resistant | 0 | 0 | | |
| PI, LPV/r, resistance possible | 0 | 0 | | |
| PI, LPV/r, sensitive | 3 | 4 | | |
| PI, NFV, resistant | 1 | 0 | | |
| PI, NFV, resistance possible | 0 | 0 | | |
| PI, NFV, sensitive | 2 | 4 | | |
| PI, RTV, resistant | 0 | 0 | | |
| PI, RTV, resistance possible | 0 | 0 | | |
| PI, RTV, sensitive | 3 | 4 | | |
| PI, SQV/r, resistant | 0 | 0 | | |
| PI, SQV/r, resistance possible | 0 | 0 | | |
| PI, SQV/r, sensitive | 3 | 4 | | |
| PI, TPV/r, resistant | 0 | 0 | | |
| PI, TPV/r, resistance possible | 0 | 0 | | |
| PI, TPV/r, sensitive | 3 | 4 | | |

Notes:

[93] - CVF Population

[94] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with AEs by using Baseline third agent treatment class overtime including Week 48

| | |
|-----------------|--|
| End point title | Number of participants with AEs by using Baseline third agent treatment class overtime including Week 48 |
|-----------------|--|

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. 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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[95] | 308 ^[96] | | |
| Units: Participants | | | | |
| Any AE, INI, n=102, 99 | 99 | 68 | | |
| Any AE, NNRTI, n=155, 155 | 148 | 116 | | |
| Any AE, PI, n=51, 54 | 47 | 36 | | |

Notes:

[95] - Safety Population

[96] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: ALT, ALP, AST and CK

| | |
|-----------------|---|
| End point title | Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: ALT, ALP, AST and CK |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[97] | 308 ^[98] | | |
| Units: International units per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, ALT, Baseline, n=51, 54 | 19.3 (± 11.23) | 18.7 (± 9.13) | | |
| PI, ALT, Week 4, n=51, 53 | 28.7 (± 20.12) | 19.8 (± 12.29) | | |
| PI, ALT, Week 8, n=34, 53 | 25.8 (± 19.28) | 19.6 (± 10.43) | | |
| PI, ALT, Week 12, n=50, 52 | 24.7 (± 17.09) | 20.1 (± 14.19) | | |
| PI, ALT, Week 16, n=48, 53 | 26.3 (± 19.89) | 20.0 (± 12.04) | | |
| PI, ALT, Week 20, n=46, 53 | 24.9 (± 18.46) | 19.0 (± 9.52) | | |
| PI, ALT, Week 24, n=47, 53 | 24.1 (± 13.75) | 19.1 (± 10.02) | | |
| PI, ALT, Week 28, n=42, 53 | 22.0 (± 12.42) | 19.4 (± 10.45) | | |
| PI, ALT, Week 32, n=45, 51 | 22.7 (± 15.18) | 18.8 (± 8.18) | | |
| PI, ALT, Week 36, n=44, 50 | 22.3 (± 15.09) | 20.7 (± 13.18) | | |
| PI, ALT, Week 40, n=42, 51 | 24.9 (± 19.63) | 19.5 (± 13.46) | | |
| PI, ALT, Week 44, n=47, 51 | 23.2 (± 17.05) | 19.3 (± 14.23) | | |
| PI, ALT, Week 48, n=43, 50 | 22.5 (± 13.28) | 19.0 (± 8.52) | | |
| INI, ALT, Baseline, n=102, 99 | 24.8 (± 15.23) | 21.2 (± 10.93) | | |
| INI, ALT, Week 4, n=99, 97 | 26.5 (± 18.35) | 21.7 (± 10.09) | | |
| INI, ALT, Week 8, n=73, 98 | 28.4 (± 22.77) | 26.8 (± 49.37) | | |

| | | | | |
|----------------------------------|-----------------|----------------|--|--|
| INI, ALT, Week 12, n=99, 95 | 23.8 (± 14.21) | 22.9 (± 16.05) | | |
| INI, ALT, Week 16, n=93, 96 | 23.2 (± 13.62) | 21.2 (± 11.24) | | |
| INI, ALT, Week 20, n=93, 97 | 23.0 (± 15.29) | 20.7 (± 9.83) | | |
| INI, ALT, Week 24, n=94, 95 | 25.7 (± 20.09) | 21.0 (± 13.40) | | |
| INI, ALT, Week 28, n=89, 93 | 21.5 (± 13.06) | 20.9 (± 14.10) | | |
| INI, ALT, Week 32, n=93, 95 | 22.5 (± 10.95) | 21.1 (± 12.32) | | |
| INI, ALT, Week 36, n=94, 95 | 26.5 (± 38.41) | 20.5 (± 9.38) | | |
| INI, ALT, Week 40, n=90, 95 | 30.2 (± 61.80) | 20.6 (± 9.20) | | |
| INI, ALT, Week 44, n=91, 94 | 23.2 (± 15.03) | 20.7 (± 10.01) | | |
| INI, ALT, Week 48, n=91, 95 | 24.4 (± 17.58) | 20.3 (± 9.79) | | |
| NNRTI, ALT, Baseline, n=155, 155 | 24.6 (± 12.67) | 24.4 (± 14.74) | | |
| NNRTI, ALT, Week 4, n=151, 153 | 21.6 (± 10.72) | 23.7 (± 11.16) | | |
| NNRTI, ALT, Week 8, n=122, 152 | 20.8 (± 10.13) | 23.7 (± 12.94) | | |
| NNRTI, ALT, Week 12, n=146, 152 | 33.9 (± 161.81) | 23.6 (± 11.27) | | |
| NNRTI, ALT, Week 16, n=143, 149 | 23.2 (± 27.18) | 22.8 (± 11.06) | | |
| NNRTI, ALT, Week 20, n=138, 152 | 22.6 (± 27.36) | 22.3 (± 11.15) | | |
| NNRTI, ALT, Week 24, n=143, 151 | 27.4 (± 85.70) | 22.9 (± 12.88) | | |
| NNRTI, ALT, Week 28, n=136, 150 | 20.6 (± 11.45) | 23.8 (± 16.00) | | |
| NNRTI, ALT, Week 32, n=137, 148 | 21.1 (± 12.69) | 23.4 (± 12.86) | | |
| NNRTI, ALT, Week 36, n=135, 147 | 21.2 (± 12.38) | 24.1 (± 13.19) | | |
| NNRTI, ALT, Week 40, n=138, 147 | 20.8 (± 10.63) | 23.9 (± 14.24) | | |
| NNRTI, ALT, Week 44, n=137, 148 | 20.0 (± 9.61) | 23.9 (± 15.22) | | |
| NNRTI, ALT, Week 48, n=131, 147 | 19.8 (± 9.62) | 23.5 (± 12.32) | | |
| PI, ALP, Baseline, n=51, 54 | 73.8 (± 24.90) | 70.2 (± 19.56) | | |
| PI, ALP, Week 4, n=51, 53 | 70.4 (± 20.03) | 67.7 (± 19.24) | | |
| PI, ALP, Week 8, n=34, 53 | 72.4 (± 34.86) | 70.9 (± 23.18) | | |
| PI, ALP, Week 12, n=50, 52 | 68.2 (± 17.49) | 71.6 (± 23.60) | | |
| PI, ALP, Week 16, n=48, 53 | 66.9 (± 15.70) | 71.2 (± 21.50) | | |
| PI, ALP, Week 20, n=46, 53 | 67.7 (± 16.36) | 70.8 (± 20.96) | | |
| PI, ALP, Week 24, n=47, 53 | 67.6 (± 16.14) | 70.3 (± 19.23) | | |
| PI, ALP, Week 28, n=42, 53 | 67.3 (± 17.71) | 73.7 (± 21.89) | | |
| PI, ALP, Week 32, n=45, 51 | 63.8 (± 16.09) | 69.8 (± 21.44) | | |
| PI, ALP, Week 36, n=44, 50 | 64.3 (± 16.50) | 71.7 (± 23.57) | | |
| PI, ALP, Week 40, n=42, 51 | 65.5 (± 13.63) | 68.5 (± 19.55) | | |
| PI, ALP, Week 44, n=47, 51 | 63.0 (± 15.76) | 69.1 (± 20.67) | | |
| PI, ALP, Week 48, n=43, 50 | 63.6 (± 14.22) | 69.9 (± 18.94) | | |
| INI, ALP, Baseline, n=102, 99 | 66.3 (± 17.31) | 64.9 (± 19.05) | | |
| INI, ALP, Week 4, n=99, 97 | 65.9 (± 17.25) | 64.4 (± 18.77) | | |
| INI, ALP, Week 8, n=73, 98 | 64.0 (± 16.21) | 69.7 (± 38.92) | | |
| INI, ALP, Week 12, n=99, 95 | 64.7 (± 16.33) | 67.7 (± 27.73) | | |
| INI, ALP, Week 16, n=93, 96 | 65.3 (± 17.01) | 64.4 (± 20.89) | | |
| INI, ALP, Week 20, n=93, 97 | 64.9 (± 16.80) | 64.2 (± 19.58) | | |
| INI, ALP, Week 24, n=94, 95 | 65.0 (± 17.08) | 64.4 (± 19.46) | | |
| INI, ALP, Week 28, n=89, 93 | 65.0 (± 15.81) | 63.3 (± 18.76) | | |
| INI, ALP, Week 32, n=93, 95 | 64.4 (± 16.12) | 62.3 (± 17.96) | | |
| INI, ALP, Week 36, n=94, 95 | 64.3 (± 18.15) | 62.2 (± 18.12) | | |
| INI, ALP, Week 40, n=90, 95 | 65.1 (± 17.07) | 62.2 (± 18.22) | | |
| INI, ALP, Week 44, n=91, 94 | 64.0 (± 16.71) | 64.1 (± 19.31) | | |
| INI, ALP, Week 48, n=91, 95 | 65.1 (± 15.98) | 63.0 (± 18.76) | | |
| NNRTI, ALP, Baseline, n=155, 155 | 84.4 (± 32.47) | 88.1 (± 28.83) | | |
| NNRTI, ALP, Week 4, n=151, 153 | 73.4 (± 26.16) | 85.6 (± 27.39) | | |

| | | | | |
|----------------------------------|------------------|-----------------|--|--|
| NNRTI, ALP, Week 8, n=122, 152 | 70.9 (± 20.00) | 87.4 (± 28.15) | | |
| NNRTI, ALP, Week 12, n=146, 152 | 72.0 (± 30.68) | 87.8 (± 28.30) | | |
| NNRTI, ALP, Week 16, n=143, 149 | 69.9 (± 22.37) | 87.7 (± 28.55) | | |
| NNRTI, ALP, Week 20, n=138, 152 | 69.3 (± 20.51) | 86.7 (± 26.18) | | |
| NNRTI, ALP, Week 24, n=143, 151 | 70.2 (± 21.08) | 88.3 (± 27.77) | | |
| NNRTI, ALP, Week 28, n=136, 150 | 69.3 (± 20.91) | 87.0 (± 28.40) | | |
| NNRTI, ALP, Week 32, n=137, 148 | 69.1 (± 21.60) | 86.5 (± 26.32) | | |
| NNRTI, ALP, Week 36, n=135, 147 | 69.3 (± 23.22) | 87.1 (± 26.24) | | |
| NNRTI, ALP, Week 40, n=138, 147 | 67.1 (± 18.98) | 87.8 (± 27.07) | | |
| NNRTI, ALP, Week 44, n=137, 148 | 68.4 (± 19.94) | 87.5 (± 26.53) | | |
| NNRTI, ALP, Week 48, n=131, 147 | 68.5 (± 21.69) | 88.6 (± 27.61) | | |
| PI, AST, Baseline, n=51, 54 | 19.7 (± 6.97) | 20.1 (± 5.66) | | |
| PI, AST, Week 4, n=51, 53 | 23.5 (± 9.76) | 22.5 (± 17.53) | | |
| PI, AST, Week 8, n=34, 53 | 23.4 (± 11.04) | 20.0 (± 5.24) | | |
| PI, AST, Week 12, n=50, 52 | 22.5 (± 11.60) | 21.8 (± 9.63) | | |
| PI, AST, Week 16, n=48, 53 | 23.7 (± 15.77) | 22.0 (± 10.39) | | |
| PI, AST, Week 20, n=46, 53 | 24.1 (± 20.53) | 20.6 (± 6.35) | | |
| PI, AST, Week 24, n=47, 53 | 21.5 (± 7.02) | 21.7 (± 11.65) | | |
| PI, AST, Week 28, n=42, 53 | 22.9 (± 9.20) | 22.0 (± 8.47) | | |
| PI, AST, Week 32, n=45, 51 | 23.0 (± 13.51) | 20.3 (± 5.57) | | |
| PI, AST, Week 36, n=44, 50 | 21.5 (± 7.88) | 21.8 (± 7.04) | | |
| PI, AST, Week 40, n=42, 51 | 25.1 (± 23.51) | 20.5 (± 7.55) | | |
| PI, AST, Week 44, n=47, 51 | 21.6 (± 8.80) | 21.4 (± 13.16) | | |
| PI, AST, Week 48, n=43, 50 | 21.6 (± 7.59) | 22.2 (± 8.85) | | |
| INI, AST, Baseline, n=102, 99 | 24.5 (± 13.03) | 22.2 (± 13.13) | | |
| INI, AST, Week 4, n=99, 97 | 24.5 (± 13.22) | 22.0 (± 10.41) | | |
| INI, AST, Week 8, n=73, 98 | 26.8 (± 25.34) | 23.6 (± 19.30) | | |
| INI, AST, Week 12, n=99, 95 | 23.2 (± 10.47) | 23.2 (± 13.10) | | |
| INI, AST, Week 16, n=93, 96 | 22.5 (± 8.78) | 22.5 (± 9.96) | | |
| INI, AST, Week 20, n=93, 97 | 22.8 (± 10.11) | 21.4 (± 6.12) | | |
| INI, AST, Week 24, n=94, 95 | 24.4 (± 12.42) | 22.0 (± 9.44) | | |
| INI, AST, Week 28, n=89, 93 | 21.3 (± 7.14) | 21.6 (± 8.49) | | |
| INI, AST, Week 32, n=93, 95 | 22.2 (± 7.77) | 21.6 (± 7.87) | | |
| INI, AST, Week 36, n=94, 95 | 23.9 (± 15.06) | 21.1 (± 5.43) | | |
| INI, AST, Week 40, n=90, 95 | 25.4 (± 18.01) | 21.8 (± 7.30) | | |
| INI, AST, Week 44, n=91, 94 | 25.6 (± 23.29) | 21.4 (± 6.51) | | |
| INI, AST, Week 48, n=91, 95 | 24.9 (± 13.88) | 22.4 (± 9.70) | | |
| NNRTI, AST, Baseline, n=155, 155 | 24.8 (± 10.99) | 23.6 (± 9.16) | | |
| NNRTI, AST, Week 4, n=151, 153 | 22.2 (± 11.35) | 23.2 (± 7.95) | | |
| NNRTI, AST, Week 8, n=122, 152 | 23.0 (± 17.16) | 22.8 (± 7.19) | | |
| NNRTI, AST, Week 12, n=146, 152 | 29.4 (± 91.34) | 23.6 (± 9.12) | | |
| NNRTI, AST, Week 16, n=143, 149 | 25.3 (± 22.91) | 22.6 (± 6.80) | | |
| NNRTI, AST, Week 20, n=138, 152 | 23.8 (± 16.12) | 22.9 (± 7.33) | | |
| NNRTI, AST, Week 24, n=143, 150 | 25.1 (± 30.40) | 23.1 (± 8.25) | | |
| NNRTI, AST, Week 28, n=136, 150 | 22.6 (± 9.49) | 24.0 (± 10.53) | | |
| NNRTI, AST, Week 32, n=137, 148 | 23.2 (± 16.69) | 25.1 (± 15.63) | | |
| NNRTI, AST, Week 36, n=135, 147 | 22.8 (± 8.90) | 23.9 (± 7.99) | | |
| NNRTI, AST, Week 40, n=138, 147 | 22.3 (± 7.66) | 23.7 (± 8.01) | | |
| NNRTI, AST, Week 44, n=137, 148 | 21.7 (± 7.11) | 23.8 (± 10.98) | | |
| NNRTI, AST, Week 48, n=131, 147 | 22.0 (± 7.86) | 24.2 (± 9.16) | | |
| PI, CK, Baseline, n=51, 54 | 121.3 (± 173.52) | 111.8 (± 66.03) | | |

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|---------------------------------|------------------------|-----------------------|--|--|
| PI, CK, Week 4, n=51, 53 | 130.0 (\pm 94.61) | 244.2 (\pm 908.06) | | |
| PI, CK, Week 8, n=34, 53 | 157.7 (\pm 174.37) | 134.2 (\pm 179.01) | | |
| PI, CK, Week 12, n=50, 52 | 124.2 (\pm 71.36) | 168.8 (\pm 406.86) | | |
| PI, CK, Week 16, n=48, 53 | 142.3 (\pm 197.96) | 127.0 (\pm 82.59) | | |
| PI, CK, Week 20, n=46, 53 | 227.9 (\pm 689.65) | 117.5 (\pm 76.83) | | |
| PI, CK, Week 24, n=47, 53 | 120.8 (\pm 72.63) | 128.9 (\pm 85.38) | | |
| PI, CK, Week 28, n=42, 53 | 185.9 (\pm 237.49) | 124.2 (\pm 96.15) | | |
| PI, CK, Week 32, n=45, 51 | 282.5 (\pm 959.49) | 110.1 (\pm 58.84) | | |
| PI, CK, Week 36, n=44, 50 | 115.5 (\pm 81.36) | 130.9 (\pm 95.59) | | |
| PI, CK, Week 40, n=42, 51 | 319.4 (\pm 1169.15) | 109.9 (\pm 53.99) | | |
| PI, CK, Week 44, n=47, 51 | 117.2 (\pm 74.25) | 114.4 (\pm 62.44) | | |
| PI, CK, Week 48, n=43, 50 | 123.5 (\pm 90.77) | 183.1 (\pm 485.07) | | |
| INI, CK, Baseline, n=102, 99 | 257.9 (\pm 565.99) | 214.3 (\pm 627.94) | | |
| INI, CK, Week 4, n=99, 97 | 225.9 (\pm 484.50) | 193.6 (\pm 415.15) | | |
| INI, CK, Week 8, n=73, 98 | 306.8 (\pm 791.76) | 158.0 (\pm 164.72) | | |
| INI, CK, Week 12, n=99, 95 | 242.5 (\pm 649.06) | 195.3 (\pm 383.74) | | |
| INI, CK, Week 16, n=93, 96 | 198.6 (\pm 335.16) | 216.4 (\pm 422.21) | | |
| INI, CK, Week 20, n=93, 97 | 200.9 (\pm 301.61) | 158.8 (\pm 156.94) | | |
| INI, CK, Week 24, n=94, 95 | 202.1 (\pm 276.49) | 178.8 (\pm 356.60) | | |
| INI, CK, Week 28, n=89, 93 | 151.1 (\pm 128.42) | 192.6 (\pm 463.71) | | |
| INI, CK, Week 32, n=93, 95 | 182.2 (\pm 202.28) | 175.1 (\pm 256.84) | | |
| INI, CK, Week 36, n=94, 95 | 190.7 (\pm 268.67) | 153.8 (\pm 151.29) | | |
| INI, CK, Week 40, n=90, 95 | 286.9 (\pm 705.76) | 178.2 (\pm 200.25) | | |
| INI, CK, Week 44, n=91, 94 | 457.7 (\pm 2054.68) | 153.6 (\pm 139.48) | | |
| INI, CK, Week 48, n=91, 95 | 278.9 (\pm 651.96) | 188.7 (\pm 339.93) | | |
| NNRTI, CK, Baseline, n=155, 155 | 180.9 (\pm 210.84) | 143.8 (\pm 118.05) | | |
| NNRTI, CK, Week 4, n=151, 153 | 192.5 (\pm 472.95) | 170.1 (\pm 226.58) | | |
| NNRTI, CK, Week 8, n=122, 152 | 290.4 (\pm 1322.89) | 141.1 (\pm 106.01) | | |
| NNRTI, CK, Week 12, n=146, 152 | 198.5 (\pm 430.65) | 168.5 (\pm 236.30) | | |
| NNRTI, CK, Week 16, n=143, 149 | 326.5 (\pm 1157.93) | 150.4 (\pm 214.31) | | |
| NNRTI, CK, Week 20, n=138, 152 | 247.2 (\pm 661.97) | 144.9 (\pm 131.72) | | |

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| NNRTI, CK, Week 24, n=143, 151 | 210.9 (± 582.66) | 161.5 (± 182.51) | | |
| NNRTI, CK, Week 28, n=136, 150 | 175.0 (± 156.46) | 197.3 (± 460.97) | | |
| NNRTI, CK, Week 32, n=137, 148 | 218.0 (± 617.20) | 238.8 (± 656.12) | | |
| NNRTI, CK, Week 36, n=135, 147 | 206.4 (± 401.19) | 155.5 (± 134.30) | | |
| NNRTI, CK, Week 40, n=138, 147 | 175.6 (± 156.39) | 166.9 (± 191.28) | | |
| NNRTI, CK, Week 44, n=137, 148 | 148.6 (± 94.67) | 159.7 (± 171.66) | | |
| NNRTI, CK, Week 48, n=131, 147 | 167.8 (± 132.83) | 171.3 (± 256.04) | | |

Notes:

[97] - Safety Population

[98] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Albumin

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| End point title | Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Albumin |
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End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: albumin to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). . Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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| End point type | Secondary |
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End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|---------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[99] | 308 ^[100] | | |
| Units: Grams per Liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Baseline, n=51, 54 | 43.9 (± 3.22) | 44.2 (± 3.36) | | |
| PI, Week 4, n=51, 53 | 44.1 (± 2.90) | 43.9 (± 2.92) | | |
| PI, Week 8, n=34, 53 | 44.6 (± 3.36) | 44.1 (± 3.32) | | |
| PI, Week 12, n=50, 52 | 43.7 (± 3.25) | 43.8 (± 3.56) | | |
| PI, Week 16, n=48, 53 | 43.8 (± 3.19) | 43.4 (± 3.36) | | |
| PI, Week 20, n=46, 53 | 43.6 (± 2.70) | 43.3 (± 3.57) | | |
| PI, Week 24, n=47, 53 | 43.5 (± 2.80) | 43.3 (± 3.09) | | |
| PI, Week 28, n=42, 53 | 43.5 (± 2.74) | 42.8 (± 3.43) | | |
| PI, Week 32, n=45, 51 | 43.2 (± 2.85) | 43.7 (± 3.31) | | |
| PI, Week 36, n=44, 50 | 43.5 (± 2.87) | 43.4 (± 3.02) | | |
| PI, Week 40, n=42, 51 | 44.2 (± 2.64) | 43.9 (± 3.11) | | |
| PI, Week 44, n=47, 51 | 43.6 (± 2.58) | 43.9 (± 3.03) | | |

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| PI, Week 48, n=43, 50 | 43.9 (± 2.97) | 44.5 (± 2.44) | | |
| INI, Baseline, n=102, 99 | 44.3 (± 3.08) | 44.9 (± 3.21) | | |
| INI, Week 4, n=99, 97 | 43.9 (± 2.91) | 43.8 (± 2.57) | | |
| INI, Week 8, n=73, 98 | 43.7 (± 3.07) | 43.9 (± 3.10) | | |
| INI, Week 12, n=99, 95 | 44.1 (± 3.01) | 44.3 (± 2.62) | | |
| INI, Week 16, n=93, 96 | 43.9 (± 2.77) | 43.7 (± 2.76) | | |
| INI, Week 20, n=93, 97 | 43.6 (± 2.70) | 44.1 (± 2.87) | | |
| INI, Week 24, n=94, 95 | 43.4 (± 3.03) | 43.9 (± 3.00) | | |
| INI, Week 28, n=89, 93 | 44.0 (± 2.97) | 43.9 (± 2.87) | | |
| INI, Week 32, n=93, 95 | 44.1 (± 2.87) | 43.7 (± 2.89) | | |
| INI, Week 36, n=94, 95 | 43.6 (± 2.74) | 43.7 (± 2.60) | | |
| INI, Week 40, n=90, 95 | 44.1 (± 2.79) | 43.6 (± 2.70) | | |
| INI, Week 44, n=91, 94 | 43.6 (± 2.96) | 43.8 (± 2.83) | | |
| INI, Week 48, n=91, 95 | 44.3 (± 2.58) | 44.3 (± 2.73) | | |
| NNRTI, Baseline, n=155, 155 | 44.1 (± 3.11) | 44.0 (± 3.10) | | |
| NNRTI, Week 4, n=151, 153 | 43.4 (± 2.83) | 43.7 (± 3.04) | | |
| NNRTI, Week 8, n=122, 152 | 43.6 (± 2.96) | 43.4 (± 3.16) | | |
| NNRTI, Week 12, n=146, 152 | 43.3 (± 2.86) | 43.7 (± 3.25) | | |
| NNRTI, Week 16, n=143, 149 | 43.3 (± 2.61) | 43.3 (± 3.27) | | |
| NNRTI, Week 20, n=138, 152 | 43.1 (± 2.75) | 43.2 (± 2.98) | | |
| NNRTI, Week 24, n=143, 151 | 43.4 (± 2.54) | 43.4 (± 3.01) | | |
| NNRTI, Week 28, n=136, 150 | 43.3 (± 2.78) | 43.2 (± 3.03) | | |
| NNRTI, Week 32, n=137, 148 | 43.2 (± 2.74) | 43.1 (± 3.43) | | |
| NNRTI, Week 36, n=135, 147 | 43.0 (± 2.86) | 43.3 (± 3.37) | | |
| NNRTI, Week 40, n=138, 147 | 43.3 (± 2.66) | 43.1 (± 3.20) | | |
| NNRTI, Week 44, n=137, 148 | 43.7 (± 2.74) | 43.2 (± 3.13) | | |
| NNRTI, Week 48, n=131, 147 | 43.4 (± 2.73) | 43.6 (± 3.14) | | |

Notes:

[99] - Safety Population

[100] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Bilirubin, direct bilirubin and creatinine

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|-----------------|---|
| End point title | Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Bilirubin, direct bilirubin and creatinine |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: bilirubin, direct bilirubin and creatinine to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[101] | 308 ^[102] | | |
| Units: Micromoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Bilirubin, Baseline, n=51, 54 | 18.3 (± 20.54) | 13.9 (± 11.07) | | |
| PI, Bilirubin, Week 4, n=51, 53 | 9.3 (± 3.81) | 14.4 (± 10.37) | | |
| PI, Bilirubin, Week 8, n=34, 53 | 8.9 (± 3.45) | 14.2 (± 10.79) | | |
| PI, Bilirubin, Week 12, n=50, 52 | 8.1 (± 3.44) | 15.6 (± 11.70) | | |
| PI, Bilirubin, Week 16, n=48, 53 | 8.7 (± 3.95) | 14.7 (± 10.78) | | |
| PI, Bilirubin, Week 20, n=46, 53 | 9.3 (± 3.60) | 15.6 (± 14.96) | | |
| PI, Bilirubin, Week 24, n=47, 53 | 9.5 (± 3.42) | 16.8 (± 16.15) | | |
| PI, Bilirubin, Week 28, n=42, 53 | 9.4 (± 4.29) | 15.0 (± 12.75) | | |
| PI, Bilirubin, Week 32, n=45, 51 | 9.7 (± 3.66) | 17.1 (± 12.45) | | |
| PI, Bilirubin, Week 36, n=44, 50 | 8.3 (± 3.17) | 16.0 (± 14.09) | | |
| PI, Bilirubin, Week 40, n=42, 51 | 9.2 (± 3.51) | 17.9 (± 18.08) | | |
| PI, Bilirubin, Week 44, n=47, 51 | 9.5 (± 3.41) | 18.1 (± 16.62) | | |
| PI, Bilirubin, Week 48, n=43, 50 | 9.3 (± 3.77) | 16.7 (± 10.73) | | |
| INI, Bilirubin, Baseline, n=102, 99 | 9.4 (± 3.94) | 9.7 (± 5.07) | | |
| INI, Bilirubin, Week 4, n=99, 97 | 9.5 (± 3.88) | 9.0 (± 4.77) | | |
| INI, Bilirubin, Week 8, n=73, 98 | 10.1 (± 4.29) | 10.7 (± 12.28) | | |
| INI, Bilirubin, Week 12, n=99, 95 | 9.9 (± 4.50) | 9.2 (± 3.91) | | |
| INI, Bilirubin, Week 16, n=93, 96 | 9.8 (± 4.29) | 9.6 (± 3.80) | | |
| INI, Bilirubin, Week 20, n=93, 97 | 10.1 (± 4.05) | 9.3 (± 3.60) | | |
| INI, Bilirubin, Week 24, n=94, 94 | 9.4 (± 4.11) | 9.1 (± 3.81) | | |
| INI, Bilirubin, Week 28, n=89, 93 | 10.3 (± 3.53) | 9.5 (± 4.67) | | |
| INI, Bilirubin, Week 32, n=93, 95 | 9.9 (± 4.42) | 8.8 (± 3.32) | | |
| INI, Bilirubin, Week 36, n=94, 95 | 9.8 (± 4.09) | 9.1 (± 3.76) | | |
| INI, Bilirubin, Week 40, n=90, 95 | 9.9 (± 4.12) | 8.9 (± 3.63) | | |
| INI, Bilirubin, Week 44, n=91, 94 | 10.1 (± 4.75) | 9.0 (± 3.40) | | |
| INI, Bilirubin, Week 48, n=91, 95 | 10.3 (± 4.37) | 8.9 (± 3.76) | | |
| NNRTI, Bilirubin, Baseline, n=155, 155 | 7.4 (± 3.30) | 7.2 (± 3.30) | | |
| NNRTI, Bilirubin, Week 4, n=151, 153 | 8.7 (± 4.10) | 6.9 (± 2.98) | | |
| NNRTI, Bilirubin, Week 8, n=122, 152 | 8.9 (± 4.01) | 6.8 (± 3.40) | | |
| NNRTI, Bilirubin, Week 12, n=146, 152 | 9.3 (± 4.66) | 7.1 (± 3.50) | | |
| NNRTI, Bilirubin, Week 16, n=143, 149 | 10.5 (± 14.51) | 6.8 (± 3.52) | | |
| NNRTI, Bilirubin, Week 20, n=138, 152 | 9.6 (± 4.63) | 7.1 (± 3.15) | | |
| NNRTI, Bilirubin, Week 24, n=143, 151 | 9.1 (± 3.93) | 6.9 (± 3.75) | | |
| NNRTI, Bilirubin, Week 28, n=136, 150 | 9.7 (± 4.17) | 6.9 (± 3.29) | | |
| NNRTI, Bilirubin, Week 32, n=137, 148 | 9.7 (± 4.55) | 6.9 (± 3.52) | | |
| NNRTI, Bilirubin, Week 36, n=135, 147 | 9.3 (± 3.72) | 7.0 (± 3.33) | | |
| NNRTI, Bilirubin, Week 40, n=138, 147 | 9.6 (± 4.21) | 7.0 (± 3.43) | | |
| NNRTI, Bilirubin, Week 44, n=137, 148 | 9.4 (± 4.03) | 7.1 (± 3.25) | | |
| NNRTI, Bilirubin, Week 48, n=131, 147 | 9.4 (± 4.28) | 7.3 (± 3.19) | | |
| PI, Direct bilirubin, Baseline, n=51, 54 | 3.6 (± 2.13) | 2.9 (± 1.68) | | |
| PI, Direct bilirubin, Week 4, n=51, 53 | 2.4 (± 1.20) | 3.3 (± 1.67) | | |
| PI, Direct bilirubin, Week 8, n=34, 53 | 2.3 (± 1.12) | 2.8 (± 1.68) | | |
| PI, Direct bilirubin, Week 12, n=50, 52 | 1.9 (± 0.80) | 3.2 (± 1.95) | | |
| PI, direct bilirubin, Week 16, n=48, 53 | 2.0 (± 0.87) | 2.9 (± 1.45) | | |
| PI, Direct bilirubin, Week 20, n=46, 53 | 2.2 (± 0.79) | 2.9 (± 2.17) | | |
| PI, Direct bilirubin, Week 24, n=47, 53 | 2.2 (± 0.75) | 3.1 (± 2.02) | | |

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| PI, Direct bilirubin, Week 28, n=42, 53 | 2.1 (± 1.08) | 2.7 (± 1.84) | | |
| PI, Direct bilirubin, Week 32, n=45, 51 | 2.2 (± 0.88) | 3.1 (± 1.84) | | |
| PI, Direct bilirubin, Week 36, n=44, 50 | 1.9 (± 0.80) | 3.1 (± 1.95) | | |
| PI, Direct bilirubin, Week 40, n=42, 51 | 2.0 (± 0.77) | 3.2 (± 2.05) | | |
| PI, Direct bilirubin, Week 44, n=47, 51 | 2.1 (± 0.83) | 3.3 (± 1.99) | | |
| PI, Direct bilirubin, Week 48, n=43, 50 | 2.3 (± 0.93) | 3.2 (± 1.71) | | |
| INI, Direct bilirubin, Baseline, n=102, 99 | 2.4 (± 0.96) | 2.3 (± 1.16) | | |
| INI, Direct bilirubin, Week 4, n=99, 97 | 2.4 (± 0.90) | 2.3 (± 1.18) | | |
| INI, Direct bilirubin, Week 8, n=73, 98 | 2.4 (± 1.02) | 3.0 (± 6.70) | | |
| INI, Direct bilirubin, Week 12, n=99, 95 | 2.3 (± 0.98) | 2.3 (± 1.06) | | |
| INI, Direct bilirubin, Week 16, n=93, 96 | 2.3 (± 1.03) | 2.1 (± 0.87) | | |
| INI, Direct bilirubin, Week 20, n=93, 97 | 2.2 (± 0.85) | 2.1 (± 0.89) | | |
| INI, Direct bilirubin, Week 24, n=94, 94 | 2.2 (± 1.02) | 2.0 (± 0.78) | | |
| INI, Direct bilirubin, Week 28, n=89, 93 | 2.2 (± 0.74) | 2.1 (± 1.12) | | |
| INI, Direct bilirubin, Week 32, n=93, 95 | 2.2 (± 0.94) | 1.9 (± 0.77) | | |
| INI, Direct bilirubin, Week 36, n=94, 95 | 2.2 (± 1.25) | 2.0 (± 0.97) | | |
| INI, Direct bilirubin, Week 40, n=90, 95 | 2.2 (± 1.06) | 2.0 (± 1.11) | | |
| INI, Direct bilirubin, Week 44, n=91, 94 | 2.3 (± 0.99) | 2.1 (± 0.95) | | |
| INI, Direct bilirubin, Week 48, n=91, 95 | 2.3 (± 0.82) | 2.2 (± 1.00) | | |
| NNRTI, Direct bilirubin, Baseline, n=155, 155 | 2.1 (± 1.00) | 1.9 (± 1.00) | | |
| NNRTI, Direct bilirubin, Week 4, n=151, 153 | 2.2 (± 1.06) | 2.0 (± 0.96) | | |
| NNRTI, Direct bilirubin, Week 8, n=122, 152 | 2.2 (± 1.10) | 1.9 (± 0.97) | | |
| NNRTI, Direct bilirubin, Week 12, n=146, 152 | 2.2 (± 1.12) | 1.9 (± 0.98) | | |
| NNRTI, Direct bilirubin, Week 16, n=143, 149 | 2.7 (± 6.95) | 1.9 (± 0.90) | | |
| NNRTI, Direct bilirubin, Week 20, n=138, 152 | 2.2 (± 1.07) | 1.7 (± 0.97) | | |
| NNRTI, Direct bilirubin, Week 24, n=143, 151 | 2.1 (± 1.04) | 1.8 (± 0.95) | | |
| NNRTI, Direct bilirubin, Week 28, n=136, 150 | 2.1 (± 1.01) | 1.7 (± 1.01) | | |
| NNRTI, Direct bilirubin, Week 32, n=137, 148 | 2.1 (± 1.08) | 1.7 (± 0.94) | | |
| NNRTI, Direct bilirubin, Week 36, n=135, 147 | 2.1 (± 1.10) | 1.7 (± 0.94) | | |
| NNRTI, Direct bilirubin, Week 40, n=138, 147 | 2.1 (± 1.18) | 1.7 (± 1.00) | | |
| NNRTI, Direct bilirubin, Week 44, n=137, 148 | 2.1 (± 0.96) | 1.8 (± 0.91) | | |
| NNRTI, Direct bilirubin, Week 48, n=131, 147 | 2.2 (± 0.98) | 1.9 (± 0.96) | | |
| PI, Creatinine, Baseline, n=51, 54 | 71.41 (± 12.315) | 70.20 (± 13.391) | | |
| PI, Creatinine, Week 4, n=51, 53 | 72.87 (± 11.632) | 72.53 (± 14.574) | | |
| PI, Creatinine, Week 8, n=34, 53 | 71.66 (± 13.012) | 71.54 (± 14.362) | | |
| PI, Creatinine, Week 12, n=50, 52 | 70.05 (± 11.609) | 73.22 (± 14.968) | | |
| PI, Creatinine, Week 16, n=48, 53 | 71.05 (± 11.778) | 73.25 (± 15.740) | | |
| PI, Creatinine, Week 20, n=46, 53 | 73.40 (± 12.191) | 75.37 (± 15.799) | | |

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|---|------------------|------------------|--|--|
| PI, Creatinine, Week 24, n=47, 53 | 72.75 (± 11.654) | 72.84 (± 14.549) | | |
| PI, Creatinine, Week 28, n=42, 53 | 75.18 (± 13.118) | 73.42 (± 14.738) | | |
| PI, Creatinine, Week 32, n=45, 51 | 74.59 (± 13.730) | 73.93 (± 15.399) | | |
| PI, Creatinine, Week 36, n=44, 50 | 74.41 (± 12.217) | 72.37 (± 14.570) | | |
| PI, Creatinine, Week 40, n=42, 51 | 74.31 (± 11.749) | 73.73 (± 15.726) | | |
| PI, Creatinine, Week 44, n=47, 51 | 75.38 (± 13.405) | 73.00 (± 14.885) | | |
| PI, Creatinine, Week 48, n=43, 50 | 76.95 (± 13.021) | 72.21 (± 15.031) | | |
| INI, Creatinine, Baseline, n=102, 99 | 88.16 (± 16.835) | 86.34 (± 17.320) | | |
| INI, Creatinine, Week 4, n=99, 95 | 86.39 (± 14.472) | 87.66 (± 16.208) | | |
| INI, Creatinine, Week 8, n=73, 98 | 85.52 (± 15.851) | 88.11 (± 17.308) | | |
| INI, Creatinine, Week 12, n=99, 95 | 85.53 (± 17.539) | 89.36 (± 17.923) | | |
| INI, Creatinine, Week 16, n=93, 96 | 84.99 (± 15.429) | 86.85 (± 17.320) | | |
| INI, Creatinine, Week 20, n=93, 97 | 85.01 (± 14.695) | 87.06 (± 16.987) | | |
| INI, Creatinine, Week 24, n=94, 94 | 84.21 (± 15.039) | 87.02 (± 16.777) | | |
| INI, Creatinine, Week 28, n=89, 93 | 84.84 (± 15.670) | 87.41 (± 17.065) | | |
| INI, Creatinine, Week 32, n=93, 95 | 85.42 (± 15.349) | 86.91 (± 15.628) | | |
| INI, Creatinine, Week 36, n=94, 95 | 84.49 (± 15.189) | 87.20 (± 15.835) | | |
| INI, Creatinine, Week 40, n=90, 95 | 85.92 (± 14.651) | 87.70 (± 17.119) | | |
| INI, Creatinine, Week 44, n=91, 94 | 84.66 (± 15.701) | 87.08 (± 16.694) | | |
| INI, Creatinine, Week 48, n=91, 95 | 85.27 (± 15.683) | 86.64 (± 15.958) | | |
| NNRTI, Creatinine, Baseline, n=155, 155 | 75.57 (± 14.604) | 75.06 (± 14.671) | | |
| NNRTI, Creatinine, Week 4, n=151, 153 | 78.57 (± 15.814) | 76.79 (± 14.908) | | |
| NNRTI, Creatinine, Week 8, n=122, 152 | 76.75 (± 15.759) | 76.17 (± 14.876) | | |
| NNRTI, Creatinine, Week 12, n=146, 152 | 76.93 (± 15.495) | 75.50 (± 14.723) | | |
| NNRTI, Creatinine, Week 16, n=143, 149 | 77.22 (± 15.406) | 77.00 (± 16.025) | | |
| NNRTI, Creatinine, Week 20, n=138, 152 | 78.32 (± 16.372) | 76.36 (± 15.744) | | |
| NNRTI, Creatinine, Week 24, n=143, 151 | 79.92 (± 21.430) | 76.26 (± 15.534) | | |
| NNRTI, Creatinine, Week 28, n=136, 150 | 79.13 (± 17.039) | 76.45 (± 15.060) | | |
| NNRTI, Creatinine, Week 32, n=137, 148 | 77.40 (± 14.117) | 77.05 (± 16.200) | | |
| NNRTI, Creatinine, Week 36, n=135, 147 | 78.15 (± 16.839) | 76.64 (± 15.734) | | |
| NNRTI, Creatinine, Week 40, n=138, 147 | 78.42 (± 16.662) | 76.04 (± 15.083) | | |

| | | | | |
|--|------------------|------------------|--|--|
| NNRTI, Creatinine, Week 44, n=137, 148 | 78.45 (± 15.909) | 76.25 (± 15.257) | | |
| NNRTI, Creatinine, Week 48, n=131, 147 | 78.91 (± 17.389) | 75.67 (± 14.794) | | |

Notes:

[101] - Safety Population

[102] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Creatinine clearance

| | |
|-----------------|---|
| End point title | Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Creatinine clearance |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: creatinine clearance to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). GFR will be estimated by the central laboratory using the CKD-EPI. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[103] | 308 ^[104] | | |
| Units: Milliliters per minute per 1.73meter ² | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Baseline, n=51, 54 | 105.2 (± 15.67) | 104.9 (± 15.22) | | |
| PI, Week 4, n=51, 53 | 103.0 (± 15.59) | 102.1 (± 15.68) | | |
| PI, Week 8, n=34, 53 | 104.3 (± 14.52) | 103.5 (± 15.61) | | |
| PI, Week 12, n=50, 52 | 107.1 (± 14.95) | 101.1 (± 15.94) | | |
| PI, Week 16, n=48, 53 | 105.4 (± 15.88) | 101.8 (± 15.99) | | |
| PI, Week 20, n=46, 53 | 102.9 (± 17.17) | 99.8 (± 16.53) | | |
| PI, Week 24, n=47, 53 | 103.3 (± 14.64) | 101.0 (± 15.54) | | |
| PI, Week 28, n=42, 53 | 100.6 (± 16.62) | 100.8 (± 14.58) | | |
| PI, Week 32, n=45, 51 | 101.0 (± 17.38) | 100.4 (± 16.04) | | |
| PI, Week 36, n=44, 50 | 100.7 (± 16.68) | 101.7 (± 14.42) | | |
| PI, Week 40, n=42, 51 | 100.2 (± 14.54) | 100.3 (± 15.51) | | |

| | | | | |
|-----------------------------|-----------------|-----------------|--|--|
| PI, Week 44, n=47, 51 | 99.8 (± 18.00) | 101.0 (± 15.31) | | |
| PI, Week 48, n=43, 50 | 98.8 (± 17.31) | 102.2 (± 15.45) | | |
| INI, Baseline, n=102, 99 | 92.3 (± 17.62) | 94.9 (± 18.82) | | |
| INI, Week 4, n=99, 95 | 93.4 (± 15.07) | 93.1 (± 18.22) | | |
| INI, Week 8, n=72, 98 | 94.4 (± 17.05) | 93.0 (± 18.12) | | |
| INI, Week 12, n=99, 93 | 94.5 (± 16.82) | 91.6 (± 18.81) | | |
| INI, Week 16, n=93, 96 | 94.9 (± 16.02) | 94.4 (± 18.30) | | |
| INI, Week 20, n=93, 97 | 95.3 (± 15.97) | 93.3 (± 17.48) | | |
| INI, Week 24, n=94, 94 | 95.6 (± 15.88) | 93.1 (± 17.21) | | |
| INI, Week 28, n=89, 93 | 95.4 (± 17.00) | 93.6 (± 17.89) | | |
| INI, Week 32, n=92, 95 | 94.8 (± 17.16) | 93.1 (± 16.94) | | |
| INI, Week 36, n=94, 95 | 95.6 (± 15.81) | 92.7 (± 15.65) | | |
| INI, Week 40, n=89, 95 | 94.8 (± 16.32) | 92.9 (± 18.15) | | |
| INI, Week 44, n=91, 94 | 94.8 (± 15.64) | 93.4 (± 17.94) | | |
| INI, Week 48, n=90, 94 | 95.4 (± 16.20) | 93.5 (± 17.00) | | |
| NNRTI, Baseline, n=155, 155 | 104.4 (± 17.78) | 103.7 (± 16.85) | | |
| NNRTI, Week 4, n=151, 153 | 100.8 (± 18.35) | 101.5 (± 17.72) | | |
| NNRTI, Week 8, n=121, 152 | 102.3 (± 17.23) | 102.2 (± 16.85) | | |
| NNRTI, Week 12, n=146, 152 | 103.1 (± 18.02) | 103.2 (± 17.47) | | |
| NNRTI, Week 16, n=143, 148 | 102.5 (± 17.66) | 101.0 (± 18.66) | | |
| NNRTI, Week 20, n=138, 152 | 101.0 (± 17.94) | 101.8 (± 17.61) | | |
| NNRTI, Week 24, n=142, 151 | 99.6 (± 18.18) | 101.7 (± 17.43) | | |
| NNRTI, Week 28, n=136, 150 | 99.9 (± 18.23) | 101.7 (± 17.20) | | |
| NNRTI, Week 32, n=137, 148 | 101.3 (± 16.10) | 101.0 (± 17.79) | | |
| NNRTI, Week 36, n=135, 147 | 100.8 (± 18.02) | 101.4 (± 17.46) | | |
| NNRTI, Week 40, n=137, 147 | 100.5 (± 18.40) | 101.6 (± 16.68) | | |
| NNRTI, Week 44, n=136, 148 | 99.9 (± 17.23) | 101.8 (± 16.96) | | |
| NNRTI, Week 48, n=131, 147 | 98.7 (± 17.35) | 102.1 (± 16.83) | | |

Notes:

[103] - Safety Population

[104] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Lipase

| | |
|-----------------|---|
| End point title | Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Lipase |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: lipase to assess the

impact of Baseline third agent treatment class (PI, NNRTI and INI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Day 1) and at Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48 | |

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[105] | 308 ^[106] | | |
| Units: Units per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Baseline, n=51, 54 | 27.6 (± 21.69) | 33.0 (± 22.44) | | |
| PI, Week 4, n=51, 53 | 25.5 (± 14.41) | 34.4 (± 20.77) | | |
| PI, Week 8, n=34, 53 | 23.4 (± 10.96) | 35.7 (± 28.85) | | |
| PI, Week 12, n=49, 52 | 26.4 (± 12.00) | 31.2 (± 15.31) | | |
| PI, Week 16, n=47, 53 | 28.1 (± 13.01) | 34.6 (± 18.14) | | |
| PI, Week 20, n=46, 53 | 25.8 (± 11.37) | 32.7 (± 16.37) | | |
| PI, Week 24, n=47, 53 | 25.8 (± 11.74) | 30.5 (± 15.48) | | |
| PI, Week 28, n=42, 53 | 26.4 (± 10.86) | 33.4 (± 15.92) | | |
| PI, Week 32, n=45, 51 | 26.9 (± 12.18) | 36.2 (± 24.23) | | |
| PI, Week 36, n=44, 50 | 27.1 (± 13.69) | 32.7 (± 17.14) | | |
| PI, Week 40, n=42, 51 | 30.5 (± 19.78) | 32.0 (± 15.16) | | |
| PI, Week 44, n=47, 51 | 27.1 (± 10.70) | 35.2 (± 18.59) | | |
| PI, Week 48, n=43, 50 | 26.3 (± 12.02) | 32.7 (± 15.62) | | |
| INI, Baseline, n=102, 99 | 29.3 (± 20.90) | 28.2 (± 16.64) | | |
| INI, Week 4, n=99, 97 | 36.8 (± 43.46) | 32.1 (± 31.31) | | |
| INI, Week 8, n=72, 98 | 28.8 (± 16.80) | 27.7 (± 12.72) | | |
| INI, Week 12, n=99, 93 | 33.1 (± 20.98) | 29.8 (± 23.81) | | |
| INI, Week 16, n=93, 97 | 34.4 (± 33.09) | 28.9 (± 14.77) | | |
| INI, Week 20, n=94, 97 | 32.0 (± 28.19) | 29.1 (± 16.34) | | |
| INI, Week 24, n=94, 95 | 32.0 (± 19.15) | 30.1 (± 21.56) | | |
| INI, Week 28, n=89, 94 | 35.1 (± 38.32) | 32.8 (± 24.85) | | |
| INI, Week 32, n=92, 95 | 32.6 (± 23.00) | 32.7 (± 21.75) | | |
| INI, Week 36, n=94, 95 | 35.0 (± 32.32) | 27.6 (± 12.20) | | |
| INI, Week 40, n=89, 95 | 33.8 (± 20.14) | 29.6 (± 14.21) | | |
| INI, Week 44, n=91, 94 | 34.6 (± 34.66) | 32.8 (± 22.45) | | |
| INI, Week 48, n=90, 94 | 35.1 (± 36.88) | 31.6 (± 23.18) | | |
| NNRTI, Baseline, n=155, 155 | 32.1 (± 24.46) | 31.8 (± 19.30) | | |
| NNRTI, Week 4, n=151, 153 | 37.6 (± 64.95) | 31.7 (± 17.60) | | |
| NNRTI, Week 8, n=121, 152 | 33.8 (± 27.26) | 33.4 (± 21.17) | | |
| NNRTI, Week 12, n=146, 152 | 35.6 (± 34.76) | 29.7 (± 14.64) | | |
| NNRTI, Week 16, n=145, 149 | 35.3 (± 32.66) | 36.8 (± 46.27) | | |
| NNRTI, Week 20, n=138, 152 | 32.0 (± 19.03) | 32.9 (± 37.34) | | |
| NNRTI, Week 24, n=142, 151 | 36.2 (± 29.08) | 37.2 (± 36.77) | | |
| NNRTI, Week 28, n=136, 150 | 33.4 (± 21.71) | 33.1 (± 17.20) | | |
| NNRTI, Week 32, n=137, 148 | 40.6 (± 83.20) | 33.6 (± 20.70) | | |
| NNRTI, Week 36, n=135, 147 | 39.9 (± 67.63) | 33.9 (± 21.66) | | |
| NNRTI, Week 40, n=138, 147 | 38.6 (± 46.34) | 32.3 (± 16.96) | | |

| | | | | |
|----------------------------|----------------|----------------|--|--|
| NNRTI, Week 44, n=136, 148 | 34.5 (± 23.27) | 32.9 (± 19.81) | | |
| NNRTI, Week 48, n=131, 146 | 36.3 (± 30.60) | 32.8 (± 20.04) | | |

Notes:

[105] - Safety Population

[106] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48

| | |
|-----------------|---|
| End point title | Absolute values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48 |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: CO₂, chloride, glucose, phosphate, potassium, sodium and urea to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[107] | 308 ^[108] | | |
| Units: Millimoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, CO ₂ , Baseline, n=51, 54 | 22.3 (± 2.53) | 22.7 (± 2.17) | | |
| PI, CO ₂ , Week 4, n=51, 53 | 23.6 (± 2.37) | 23.4 (± 2.28) | | |
| PI, CO ₂ , Week 8, n=34, 53 | 23.0 (± 1.95) | 23.0 (± 2.53) | | |
| PI, CO ₂ , Week 12, n=50, 52 | 22.9 (± 2.14) | 22.9 (± 2.41) | | |
| PI, CO ₂ , Week 16, n=48, 53 | 23.0 (± 2.07) | 22.9 (± 2.32) | | |
| PI, CO ₂ , Week 20, n=46, 53 | 23.1 (± 2.04) | 22.7 (± 2.59) | | |
| PI, CO ₂ , Week 24, n=47, 53 | 22.7 (± 1.95) | 22.8 (± 2.62) | | |
| PI, CO ₂ , Week 28, n=42, 53 | 22.7 (± 2.31) | 22.5 (± 2.48) | | |
| PI, CO ₂ , Week 32, n=45, 51 | 22.6 (± 2.22) | 22.6 (± 2.84) | | |
| PI, CO ₂ , Week 36, n=44, 50 | 22.6 (± 2.21) | 22.4 (± 2.36) | | |
| PI, CO ₂ , Week 40, n=42, 51 | 22.8 (± 2.24) | 23.1 (± 2.37) | | |
| PI, CO ₂ , Week 44, n=47, 51 | 22.9 (± 1.94) | 23.1 (± 2.37) | | |
| PI, CO ₂ , Week 48, n=43, 50 | 23.0 (± 2.01) | 22.7 (± 2.19) | | |
| INI, CO ₂ , Baseline, n=102, 99 | 22.8 (± 2.09) | 22.9 (± 2.08) | | |
| INI, CO ₂ , Week 4, n=99, 97 | 23.7 (± 2.36) | 23.7 (± 2.28) | | |
| INI, CO ₂ , Week 8, n=73, 98 | 23.0 (± 2.10) | 23.6 (± 2.20) | | |
| INI, CO ₂ , Week 12, n=99, 95 | 23.2 (± 2.07) | 23.3 (± 2.26) | | |
| INI, CO ₂ , Week 16, n=93, 96 | 22.8 (± 2.10) | 23.5 (± 2.39) | | |
| INI, CO ₂ , Week 20, n=93, 97 | 22.8 (± 2.11) | 23.6 (± 2.14) | | |
| INI, CO ₂ , Week 24, n=94, 95 | 22.8 (± 2.22) | 23.1 (± 2.21) | | |

| | | | | |
|---------------------------------------|----------------|----------------|--|--|
| INI, CO2, Week 28, n=89, 93 | 22.5 (± 2.21) | 23.1 (± 2.14) | | |
| INI, CO2, Week 32, n=93, 95 | 22.8 (± 2.17) | 23.0 (± 2.09) | | |
| INI, CO2, Week 36, n=94, 95 | 22.8 (± 1.90) | 23.5 (± 2.12) | | |
| INI, CO2, Week 40, n=90, 95 | 23.1 (± 2.07) | 23.2 (± 2.09) | | |
| INI, CO2, Week 44, n=91, 94 | 23.1 (± 2.08) | 23.7 (± 2.11) | | |
| INI, CO2, Week 48, n=91, 95 | 22.9 (± 1.97) | 23.3 (± 2.32) | | |
| NNRTI, CO2, Baseline, n=155, 155 | 22.7 (± 2.41) | 22.3 (± 2.35) | | |
| NNRTI, CO2, Week 4, n=151, 153 | 23.7 (± 2.63) | 23.0 (± 2.24) | | |
| NNRTI, CO2, Week 8, n=122, 152 | 23.2 (± 2.28) | 23.1 (± 2.61) | | |
| NNRTI, CO2, Week 12, n=146, 152 | 23.2 (± 2.18) | 22.8 (± 2.39) | | |
| NNRTI, CO2, Week 16, n=143, 149 | 23.0 (± 2.24) | 22.8 (± 2.23) | | |
| NNRTI, CO2, Week 20, n=138, 152 | 22.9 (± 2.24) | 22.5 (± 2.20) | | |
| NNRTI, CO2, Week 24, n=143, 150 | 23.0 (± 2.49) | 22.7 (± 2.45) | | |
| NNRTI, CO2, Week 28, n=136, 150 | 22.8 (± 2.58) | 22.6 (± 2.27) | | |
| NNRTI, CO2, Week 32, n=137, 148 | 22.5 (± 2.11) | 22.7 (± 2.29) | | |
| NNRTI, CO2, Week 36, n=135, 147 | 22.8 (± 2.38) | 22.8 (± 2.27) | | |
| NNRTI, CO2, Week 40, n=138, 147 | 23.1 (± 2.40) | 22.8 (± 2.68) | | |
| NNRTI, CO2, Week 44, n=137, 148 | 23.0 (± 2.35) | 22.8 (± 2.38) | | |
| NNRTI, CO2, Week 48, n=131, 147 | 22.5 (± 2.55) | 22.6 (± 2.29) | | |
| PI, Chloride, Baseline, n=51, 54 | 104.0 (± 1.46) | 103.5 (± 2.61) | | |
| PI, Chloride, Week 4, n=51, 53 | 104.5 (± 1.80) | 104.0 (± 2.10) | | |
| PI, Chloride, Week 8, n=34, 53 | 104.4 (± 2.35) | 104.2 (± 2.28) | | |
| PI, Chloride, Week 12, n=50, 52 | 104.4 (± 2.02) | 104.3 (± 2.13) | | |
| PI, Chloride, Week 16, n=48, 53 | 104.4 (± 2.08) | 104.5 (± 2.10) | | |
| PI, Chloride, Week 20, n=46, 53 | 104.8 (± 1.98) | 104.2 (± 1.97) | | |
| PI, Chloride, Week 24, n=47, 53 | 105.1 (± 1.85) | 104.7 (± 2.02) | | |
| PI, Chloride, Week 28, n=42, 53 | 105.3 (± 1.88) | 104.6 (± 2.47) | | |
| PI, Chloride, Week 32, n=45, 51 | 105.0 (± 2.32) | 104.4 (± 1.92) | | |
| PI, Chloride, Week 36, n=44, 50 | 105.0 (± 2.17) | 104.4 (± 2.27) | | |
| PI, Chloride, Week 40, n=42, 51 | 105.2 (± 2.27) | 104.5 (± 2.31) | | |
| PI, Chloride, Week 44, n=47, 51 | 105.1 (± 1.84) | 104.5 (± 1.88) | | |
| PI, Chloride, Week 48, n=43, 50 | 104.4 (± 1.72) | 104.3 (± 1.88) | | |
| INI, Chloride, Baseline, n=102, 99 | 103.6 (± 2.03) | 103.5 (± 2.26) | | |
| INI, Chloride, Week 4, n=99, 97 | 104.0 (± 2.17) | 104.0 (± 2.15) | | |
| INI, Chloride, Week 8, n=73, 98 | 104.1 (± 2.16) | 103.5 (± 2.58) | | |
| INI, Chloride, Week 12, n=99, 95 | 104.1 (± 2.31) | 104.0 (± 2.32) | | |
| INI, Chloride, Week 16, n=93, 96 | 104.7 (± 2.05) | 104.2 (± 2.26) | | |
| INI, Chloride, Week 20, n=93, 97 | 104.8 (± 2.39) | 103.8 (± 2.36) | | |
| INI, Chloride, Week 24, n=94, 95 | 104.3 (± 2.30) | 104.1 (± 2.50) | | |
| INI, Chloride, Week 28, n=89, 93 | 104.7 (± 1.92) | 104.0 (± 2.16) | | |
| INI, Chloride, Week 32, n=93, 95 | 104.5 (± 2.33) | 104.2 (± 2.47) | | |
| INI, Chloride, Week 36, n=94, 95 | 104.6 (± 2.04) | 104.1 (± 2.40) | | |
| INI, Chloride, Week 40, n=90, 95 | 104.4 (± 1.94) | 103.9 (± 2.48) | | |
| INI, Chloride, Week 44, n=91, 94 | 104.5 (± 2.12) | 104.0 (± 2.27) | | |
| INI, Chloride, Week 48, n=91, 95 | 104.2 (± 2.43) | 103.2 (± 2.26) | | |
| NNRTI, Chloride, Baseline, n=155, 155 | 103.9 (± 2.18) | 104.0 (± 2.37) | | |
| NNRTI, Chloride, Week 4, n=151, 153 | 104.3 (± 2.21) | 104.6 (± 2.29) | | |
| NNRTI, Chloride, Week 8, n=122, 152 | 104.4 (± 2.31) | 104.7 (± 2.22) | | |
| NNRTI, Chloride, Week 12, n=146, 152 | 104.3 (± 2.33) | 104.5 (± 2.23) | | |
| NNRTI, Chloride, Week 16, n=143, 149 | 104.4 (± 2.37) | 104.8 (± 2.34) | | |
| NNRTI, Chloride, Week 20, n=138, 152 | 104.6 (± 2.55) | 105.1 (± 2.38) | | |
| NNRTI, Chloride, Week 24, n=143, 151 | 104.4 (± 2.52) | 105.1 (± 2.18) | | |

| | | | | |
|--------------------------------------|------------------|------------------|--|--|
| NNRTI, Chloride, Week 28, n=136, 150 | 104.7 (± 2.41) | 105.3 (± 2.31) | | |
| NNRTI, Chloride, Week 32, n=137, 148 | 104.7 (± 2.68) | 105.1 (± 2.26) | | |
| NNRTI, Chloride, Week 36, n=135, 147 | 105.0 (± 2.28) | 105.1 (± 2.30) | | |
| NNRTI, Chloride, Week 40, n=138, 147 | 104.7 (± 2.36) | 105.0 (± 2.70) | | |
| NNRTI, Chloride, Week 44, n=137, 148 | 104.6 (± 2.17) | 105.0 (± 2.32) | | |
| NNRTI, Chloride, Week 48, n=131, 147 | 104.6 (± 2.54) | 104.5 (± 2.46) | | |
| PI, Glucose, Baseline, n=51, 53 | 5.11 (± 0.878) | 5.03 (± 0.505) | | |
| PI, Glucose, Week 4, n=43, 43 | 5.06 (± 0.481) | 5.29 (± 0.452) | | |
| PI, Glucose, Week 8, n=25, 41 | 5.11 (± 0.456) | 5.18 (± 0.462) | | |
| PI, Glucose, Week 12, n=40, 43 | 5.21 (± 0.533) | 5.25 (± 0.535) | | |
| PI, Glucose, Week 16, n=39, 44 | 5.24 (± 0.800) | 5.26 (± 0.614) | | |
| PI, Glucose, Week 20, n=35, 42 | 5.11 (± 0.580) | 5.29 (± 0.718) | | |
| PI, Glucose, Week 24, n=38, 43 | 5.31 (± 0.526) | 5.29 (± 0.747) | | |
| PI, Glucose, Week 28, n=32, 43 | 5.16 (± 0.651) | 5.12 (± 0.512) | | |
| PI, Glucose, Week 32, n=36, 42 | 5.37 (± 0.700) | 5.31 (± 0.643) | | |
| PI, Glucose, Week 36, n=35, 42 | 5.13 (± 0.525) | 5.23 (± 0.513) | | |
| PI, Glucose, Week 40, n=34, 41 | 5.31 (± 0.464) | 5.17 (± 0.555) | | |
| PI, Glucose, Week 44, n=40, 40 | 5.13 (± 0.681) | 5.20 (± 0.408) | | |
| PI, Glucose, Week 48, n=39, 48 | 5.16 (± 0.647) | 5.18 (± 0.661) | | |
| INI, Glucose, Baseline, n=98, 96 | 5.06 (± 0.638) | 5.25 (± 0.801) | | |
| INI, Glucose, Week 4, n=55, 54 | 5.39 (± 0.771) | 5.37 (± 1.043) | | |
| INI, Glucose, Week 8, n=36, 58 | 5.16 (± 0.584) | 5.49 (± 1.307) | | |
| INI, Glucose, Week 12, n=53, 56 | 5.50 (± 1.317) | 5.51 (± 1.414) | | |
| INI, Glucose, Week 16, n=54, 53 | 5.41 (± 1.727) | 5.25 (± 0.624) | | |
| INI, Glucose, Week 20, n=52, 58 | 5.36 (± 0.674) | 5.21 (± 0.793) | | |
| INI, Glucose, Week 24, n=61, 62 | 5.34 (± 0.660) | 5.36 (± 0.753) | | |
| INI, Glucose, Week 28, n=53, 63 | 5.32 (± 0.817) | 5.45 (± 0.940) | | |
| INI, Glucose, Week 32, n=54, 56 | 5.57 (± 1.260) | 5.52 (± 0.839) | | |
| INI, Glucose, Week 36, n=53, 58 | 5.46 (± 0.697) | 5.34 (± 1.142) | | |
| INI, Glucose, Week 40, n=59, 63 | 5.53 (± 0.931) | 5.46 (± 0.765) | | |
| INI, Glucose, Week 44, n=54, 57 | 5.40 (± 1.020) | 5.43 (± 0.637) | | |
| INI, Glucose, Week 48, n=84, 91 | 5.16 (± 0.549) | 5.24 (± 0.752) | | |
| NNRTI, Glucose, Baseline, n=152, 150 | 4.93 (± 0.697) | 5.17 (± 1.201) | | |
| NNRTI, Glucose, Week 4, n=118, 129 | 5.11 (± 0.798) | 5.48 (± 1.490) | | |
| NNRTI, Glucose, Week 8, n=92, 119 | 5.17 (± 1.204) | 5.35 (± 1.030) | | |
| NNRTI, Glucose, Week 12, n=113, 122 | 5.04 (± 0.856) | 5.30 (± 1.067) | | |
| NNRTI, Glucose, Week 16, n=116, 119 | 5.12 (± 0.914) | 5.45 (± 1.683) | | |
| NNRTI, Glucose, Week 20, n=107, 121 | 5.16 (± 0.802) | 5.48 (± 1.476) | | |
| NNRTI, Glucose, Week 24, n=116, 124 | 5.16 (± 0.944) | 5.36 (± 0.914) | | |
| NNRTI, Glucose, Week 28, n=105, 120 | 5.08 (± 0.635) | 5.40 (± 0.934) | | |
| NNRTI, Glucose, Week 32, n=104, 121 | 5.18 (± 1.000) | 5.47 (± 1.316) | | |
| NNRTI, Glucose, Week 36, n=103, 120 | 5.07 (± 0.856) | 5.49 (± 1.857) | | |
| NNRTI, Glucose, Week 40, n=102, 114 | 5.16 (± 0.776) | 5.53 (± 1.558) | | |
| NNRTI, Glucose, Week 44, n=99, 116 | 5.15 (± 0.877) | 5.53 (± 1.708) | | |
| NNRTI, Glucose, Week 48, n=119, 138 | 5.01 (± 0.640) | 5.23 (± 1.160) | | |
| PI, Phosphate, Baseline, n=51, 54 | 1.048 (± 0.1523) | 1.060 (± 0.1719) | | |
| PI, Phosphate, Week 4, n=51, 53 | 1.116 (± 0.1648) | 1.069 (± 0.1647) | | |
| PI, Phosphate, Week 8, n=34, 53 | 1.119 (± 0.1891) | 1.041 (± 0.1664) | | |
| PI, Phosphate, Week 12, n=50, 52 | 1.073 (± 0.1788) | 1.064 (± 0.1872) | | |

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| PI, Phosphate, Week 16, n=48, 53 | 1.111 (\pm 0.2006) | 1.051 (\pm 0.1849) | | |
| PI, Phosphate, Week 20, n=46, 53 | 1.119 (\pm 0.1689) | 1.076 (\pm 0.2187) | | |
| PI, Phosphate, Week 24, n=47, 53 | 1.086 (\pm 0.1647) | 1.077 (\pm 0.1631) | | |
| PI, Phosphate, Week 28, n=42, 53 | 1.085 (\pm 0.1803) | 1.076 (\pm 0.1970) | | |
| PI, Phosphate, Week 32, n=45, 51 | 1.109 (\pm 0.1869) | 1.081 (\pm 0.1769) | | |
| PI, Phosphate, Week 36, n=44, 50 | 1.084 (\pm 0.1659) | 1.058 (\pm 0.1830) | | |
| PI, Phosphate, Week 40, n=42, 51 | 1.067 (\pm 0.2020) | 1.053 (\pm 0.1932) | | |
| PI, Phosphate, Week 44, n=47, 51 | 1.084 (\pm 0.1785) | 1.063 (\pm 0.2227) | | |
| PI, Phosphate, Week 48, n=43, 50 | 1.095 (\pm 0.1636) | 1.070 (\pm 0.1804) | | |
| INI, Phosphate, Baseline, n=102, 99 | 1.045 (\pm 0.1687) | 1.063 (\pm 0.1700) | | |
| INI, Phosphate, Week 4, n=99, 97 | 1.080 (\pm 0.1725) | 1.082 (\pm 0.1857) | | |
| INI, Phosphate, Week 8, n=73, 98 | 1.086 (\pm 0.1901) | 1.071 (\pm 0.2001) | | |
| INI, Phosphate, Week 12, n=99, 95 | 1.068 (\pm 0.1970) | 1.078 (\pm 0.1823) | | |
| INI, Phosphate, Week 16, n=93, 96 | 1.063 (\pm 0.1623) | 1.061 (\pm 0.1702) | | |
| INI, Phosphate, Week 20, n=93, 97 | 1.046 (\pm 0.1717) | 1.091 (\pm 0.1757) | | |
| INI, Phosphate, Week 24, n=94, 95 | 1.066 (\pm 0.1661) | 1.052 (\pm 0.1921) | | |
| INI, Phosphate, Week 28, n=89, 93 | 1.060 (\pm 0.1602) | 1.065 (\pm 0.1835) | | |
| INI, Phosphate, Week 32, n=93, 95 | 1.045 (\pm 0.1649) | 1.045 (\pm 0.1569) | | |
| INI, Phosphate, Week 36, n=94, 95 | 1.032 (\pm 0.1572) | 1.059 (\pm 0.1800) | | |
| INI, Phosphate, Week 40, n=90, 95 | 1.054 (\pm 0.1838) | 1.062 (\pm 0.1731) | | |
| INI, Phosphate, Week 44, n=91, 94 | 1.043 (\pm 0.1805) | 1.066 (\pm 0.2029) | | |
| INI, Phosphate, Week 48, n=91, 95 | 1.072 (\pm 0.1721) | 1.066 (\pm 0.1918) | | |
| NNRTI, Phosphate, Baseline, n=155, 155 | 1.038 (\pm 0.1905) | 1.040 (\pm 0.1741) | | |
| NNRTI, Phosphate, Week 4, n=151, 153 | 1.128 (\pm 0.1867) | 1.056 (\pm 0.1764) | | |
| NNRTI, Phosphate, Week 8, n=122, 152 | 1.097 (\pm 0.1994) | 1.024 (\pm 0.1784) | | |
| NNRTI, Phosphate, Week 12, n=146, 152 | 1.091 (\pm 0.1838) | 1.051 (\pm 0.2002) | | |
| NNRTI, Phosphate, Week 16, n=143, 149 | 1.082 (\pm 0.1827) | 1.046 (\pm 0.1700) | | |
| NNRTI, Phosphate, Week 20, n=138, 152 | 1.076 (\pm 0.1763) | 1.037 (\pm 0.1806) | | |
| NNRTI, Phosphate, Week 24, n=143, 151 | 1.091 (\pm 0.1914) | 1.052 (\pm 0.1882) | | |
| NNRTI, Phosphate, Week 28, n=136, 150 | 1.076 (\pm 0.1764) | 1.038 (\pm 0.1585) | | |
| NNRTI, Phosphate, Week 32, n=137, 148 | 1.057 (\pm 0.1722) | 1.050 (\pm 0.1874) | | |

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| NNRTI, Phosphate, Week 36, n=135, 147 | 1.055 (± 0.1790) | 1.039 (± 0.1793) | | |
| NNRTI, Phosphate, Week 40, n=138, 147 | 1.071 (± 0.1689) | 1.033 (± 0.1724) | | |
| NNRTI, Phosphate, Week 44, n=137, 148 | 1.076 (± 0.1795) | 1.040 (± 0.1693) | | |
| NNRTI, Phosphate, Week 48, n=131, 147 | 1.075 (± 0.1941) | 1.037 (± 0.1789) | | |
| PI, Potassium, Baseline, n=51, 54 | 4.13 (± 0.288) | 4.10 (± 0.308) | | |
| PI, Potassium, Week 4, n=51, 53 | 4.25 (± 0.355) | 4.31 (± 0.395) | | |
| PI, Potassium, Week 8, n=34, 53 | 4.18 (± 0.283) | 4.19 (± 0.331) | | |
| PI, Potassium, Week 12, n=50, 52 | 4.25 (± 0.335) | 4.31 (± 0.364) | | |
| PI, Potassium, Week 16, n=48, 53 | 4.16 (± 0.322) | 4.30 (± 0.359) | | |
| PI, Potassium, Week 20, n=46, 53 | 4.18 (± 0.291) | 4.29 (± 0.314) | | |
| PI, Potassium, Week 24, n=47, 53 | 4.15 (± 0.335) | 4.30 (± 0.379) | | |
| PI, Potassium, Week 28, n=42, 53 | 4.21 (± 0.342) | 4.26 (± 0.348) | | |
| PI, Potassium, Week 32, n=45, 51 | 4.15 (± 0.326) | 4.31 (± 0.367) | | |
| PI, Potassium, Week 36, n=44, 50 | 4.25 (± 0.345) | 4.26 (± 0.378) | | |
| PI, Potassium, Week 40, n=42, 51 | 4.23 (± 0.293) | 4.26 (± 0.363) | | |
| PI, Potassium, Week 44, n=47, 51 | 4.24 (± 0.348) | 4.32 (± 0.375) | | |
| PI, Potassium, Week 48, n=43, 50 | 4.15 (± 0.292) | 4.12 (± 0.320) | | |
| INI, Potassium, Baseline, n=102, 99 | 4.17 (± 0.245) | 4.18 (± 0.289) | | |
| INI, Potassium, Week 4, n=99, 97 | 4.20 (± 0.311) | 4.26 (± 0.359) | | |
| INI, Potassium, Week 8, n=73, 98 | 4.14 (± 0.306) | 4.24 (± 0.462) | | |
| INI, Potassium, Week 12, n=99, 95 | 4.19 (± 0.340) | 4.18 (± 0.291) | | |
| INI, Potassium, Week 16, n=93, 96 | 4.15 (± 0.317) | 4.19 (± 0.297) | | |
| INI, Potassium, Week 20, n=93, 97 | 4.20 (± 0.299) | 4.18 (± 0.289) | | |
| INI, Potassium, Week 24, n=94, 95 | 4.19 (± 0.304) | 4.21 (± 0.304) | | |
| INI, Potassium, Week 28, n=89, 93 | 4.19 (± 0.412) | 4.22 (± 0.341) | | |
| INI, Potassium, Week 32, n=93, 95 | 4.20 (± 0.358) | 4.19 (± 0.307) | | |
| INI, Potassium, Week 36, n=94, 95 | 4.19 (± 0.365) | 4.23 (± 0.332) | | |
| INI, Potassium, Week 40, n=90, 95 | 4.18 (± 0.332) | 4.19 (± 0.297) | | |
| INI, Potassium, Week 44, n=91, 94 | 4.18 (± 0.309) | 4.17 (± 0.314) | | |
| INI, Potassium, Week 48, n=91, 95 | 4.15 (± 0.266) | 4.16 (± 0.305) | | |
| NNRTI, Potassium, Baseline, n=155, 155 | 4.16 (± 0.302) | 4.18 (± 0.331) | | |
| NNRTI, Potassium, Week 4, n=151, 153 | 4.21 (± 0.287) | 4.28 (± 0.333) | | |
| NNRTI, Potassium, Week 8, n=122, 152 | 4.17 (± 0.295) | 4.23 (± 0.366) | | |
| NNRTI, Potassium, Week 12, n=146, 152 | 4.18 (± 0.322) | 4.26 (± 0.341) | | |
| NNRTI, Potassium, Week 16, n=143, 149 | 4.20 (± 0.313) | 4.23 (± 0.320) | | |
| NNRTI, Potassium, Week 20, n=138, 152 | 4.20 (± 0.326) | 4.21 (± 0.337) | | |
| NNRTI, Potassium, Week 24, n=143, 150 | 4.19 (± 0.259) | 4.22 (± 0.341) | | |
| NNRTI, Potassium, Week 28, n=136, 150 | 4.18 (± 0.301) | 4.25 (± 0.434) | | |
| NNRTI, Potassium, Week 32, n=137, 148 | 4.17 (± 0.388) | 4.20 (± 0.349) | | |
| NNRTI, Potassium, Week 36, n=135, 147 | 4.17 (± 0.289) | 4.22 (± 0.343) | | |
| NNRTI, Potassium, Week 40, n=138, 147 | 4.20 (± 0.283) | 4.26 (± 0.321) | | |
| NNRTI, Potassium, Week 44, n=137, 148 | 4.23 (± 0.324) | 4.24 (± 0.374) | | |

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| NNRTI, Potassium, Week 48, n=131, 147 | 4.14 (± 0.271) | 4.17 (± 0.352) | | |
| PI, Sodium, Baseline, n=51, 54 | 138.9 (± 2.15) | 138.7 (± 2.10) | | |
| PI, Sodium, Week 4, n=51, 53 | 139.3 (± 1.64) | 139.0 (± 2.08) | | |
| PI, Sodium, Week 8, n=34, 53 | 139.6 (± 2.10) | 139.0 (± 1.95) | | |
| PI, Sodium, Week 12, n=50, 52 | 139.3 (± 1.76) | 139.4 (± 2.03) | | |
| PI, Sodium, Week 16, n=48, 53 | 139.4 (± 2.18) | 139.0 (± 1.75) | | |
| PI, Sodium, Week 20, n=46, 53 | 139.6 (± 1.71) | 139.1 (± 1.97) | | |
| PI, Sodium, Week 24, n=47, 53 | 139.4 (± 2.08) | 139.1 (± 2.07) | | |
| PI, Sodium, Week 28, n=42, 53 | 140.3 (± 1.59) | 139.5 (± 2.49) | | |
| PI, Sodium, Week 32, n=45, 51 | 139.4 (± 2.14) | 139.3 (± 2.28) | | |
| PI, Sodium, Week 36, n=44, 50 | 139.7 (± 1.63) | 139.4 (± 2.32) | | |
| PI, Sodium, Week 40, n=42, 51 | 139.8 (± 1.94) | 139.4 (± 1.93) | | |
| PI, Sodium, Week 44, n=47, 51 | 139.7 (± 1.78) | 139.4 (± 2.09) | | |
| PI, Sodium, Week 48, n=43, 50 | 139.8 (± 1.86) | 139.6 (± 1.90) | | |
| INI, Sodium, Baseline, n=102, 99 | 138.8 (± 1.62) | 139.0 (± 1.67) | | |
| INI, Sodium, Week 4, n=99, 97 | 139.2 (± 1.58) | 139.1 (± 1.72) | | |
| INI, Sodium, Week 8, n=73, 98 | 138.8 (± 2.00) | 138.8 (± 1.79) | | |
| INI, Sodium, Week 12, n=99, 95 | 139.1 (± 1.97) | 139.0 (± 1.88) | | |
| INI, Sodium, Week 16, n=93, 96 | 139.1 (± 1.87) | 139.4 (± 1.89) | | |
| INI, Sodium, Week 20, n=93, 97 | 139.4 (± 1.92) | 139.2 (± 1.67) | | |
| INI, Sodium, Week 24, n=94, 95 | 139.3 (± 1.86) | 139.1 (± 1.91) | | |
| INI, Sodium, Week 28, n=89, 93 | 139.4 (± 1.65) | 138.8 (± 1.67) | | |
| INI, Sodium, Week 32, n=93, 95 | 139.4 (± 1.63) | 139.2 (± 1.68) | | |
| INI, Sodium, Week 36, n=94, 95 | 139.2 (± 1.84) | 139.4 (± 1.99) | | |
| INI, Sodium, Week 40, n=90, 95 | 139.3 (± 2.01) | 139.3 (± 1.83) | | |
| INI, Sodium, Week 44, n=91, 94 | 139.3 (± 1.67) | 139.4 (± 1.88) | | |
| INI, Sodium, Week 48, n=91, 95 | 139.3 (± 1.98) | 139.0 (± 1.76) | | |
| NNRTI, Sodium, Baseline, n=155, 155 | 139.1 (± 2.00) | 139.2 (± 1.68) | | |
| NNRTI, Sodium, Week 4, n=151, 153 | 139.4 (± 1.79) | 139.2 (± 1.90) | | |
| NNRTI, Sodium, Week 8, n=122, 152 | 139.1 (± 1.91) | 139.2 (± 1.76) | | |
| NNRTI, Sodium, Week 12, n=146, 152 | 139.2 (± 1.78) | 139.2 (± 1.77) | | |
| NNRTI, Sodium, Week 16, n=143, 149 | 139.0 (± 1.99) | 139.0 (± 2.06) | | |
| NNRTI, Sodium, Week 20, n=138, 152 | 139.0 (± 1.87) | 139.5 (± 1.83) | | |
| NNRTI, Sodium, Week 24, n=143, 151 | 139.2 (± 1.83) | 139.4 (± 1.94) | | |
| NNRTI, Sodium, Week 28, n=136, 150 | 139.3 (± 1.84) | 139.4 (± 1.99) | | |
| NNRTI, Sodium, Week 32, n=137, 148 | 139.2 (± 1.68) | 139.7 (± 1.75) | | |
| NNRTI, Sodium, Week 36, n=135, 147 | 139.4 (± 1.80) | 139.7 (± 2.19) | | |
| NNRTI, Sodium, Week 40, n=138, 147 | 139.4 (± 1.87) | 139.7 (± 2.06) | | |
| NNRTI, Sodium, Week 44, n=137, 148 | 139.5 (± 1.88) | 139.7 (± 1.92) | | |
| NNRTI, Sodium, Week 48, n=131, 147 | 139.4 (± 1.93) | 139.5 (± 1.82) | | |
| PI, Urea, Baseline, n=51, 54 | 4.97 (± 1.409) | 4.89 (± 1.316) | | |
| PI, Urea, Week 4, n=51, 53 | 4.99 (± 1.210) | 4.91 (± 1.455) | | |
| PI, Urea, Week 8, n=34, 53 | 5.10 (± 1.353) | 4.88 (± 1.447) | | |
| PI, Urea, Week 12, n=50, 52 | 5.03 (± 1.368) | 4.85 (± 1.480) | | |
| PI, Urea, Week 16, n=48, 53 | 5.20 (± 1.295) | 5.09 (± 1.754) | | |
| PI, Urea, Week 20, n=46, 53 | 5.18 (± 1.216) | 5.07 (± 1.535) | | |
| PI, Urea, Week 24, n=47, 53 | 5.44 (± 1.587) | 5.00 (± 1.414) | | |
| PI, Urea, Week 28, n=42, 53 | 5.21 (± 1.358) | 4.90 (± 1.530) | | |
| PI, Urea, Week 32, n=45, 51 | 5.13 (± 1.135) | 5.09 (± 1.482) | | |
| PI, Urea, Week 36, n=44, 50 | 4.99 (± 1.310) | 4.78 (± 1.411) | | |
| PI, Urea, Week 40, n=42, 51 | 5.35 (± 1.227) | 5.30 (± 1.758) | | |

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| PI, Urea, Week 44, n=47, 51 | 5.38 (± 1.483) | 5.10 (± 1.517) | | |
| PI, Urea, Week 48, n=43, 50 | 5.22 (± 1.469) | 5.11 (± 1.489) | | |
| INI, Urea, Baseline, n=102, 99 | 5.76 (± 1.528) | 5.61 (± 1.894) | | |
| INI, Urea, Week 4, n=99, 97 | 5.63 (± 1.471) | 5.77 (± 1.676) | | |
| INI, Urea, Week 8, n=73, 98 | 5.80 (± 1.617) | 5.60 (± 1.607) | | |
| INI, Urea, Week 12, n=99, 95 | 5.81 (± 1.536) | 5.83 (± 1.724) | | |
| INI, Urea, Week 16, n=93, 96 | 5.76 (± 1.577) | 5.70 (± 1.574) | | |
| INI, Urea, Week 20, n=93, 97 | 5.75 (± 1.640) | 5.76 (± 1.580) | | |
| INI, Urea, Week 24, n=94, 95 | 5.84 (± 1.578) | 5.72 (± 1.774) | | |
| INI, Urea, Week 28, n=89, 93 | 5.76 (± 1.593) | 5.65 (± 1.435) | | |
| INI, Urea, Week 32, n=93, 95 | 5.67 (± 1.537) | 5.63 (± 1.477) | | |
| INI, Urea, Week 36, n=94, 95 | 5.67 (± 1.670) | 5.53 (± 1.456) | | |
| INI, Urea, Week 40, n=90, 95 | 5.81 (± 1.669) | 5.66 (± 1.593) | | |
| INI, Urea, Week 44, n=91, 94 | 5.59 (± 1.607) | 5.46 (± 1.368) | | |
| INI, Urea, Week 48, n=91, 95 | 5.83 (± 1.654) | 5.50 (± 1.468) | | |
| NNRTI, Urea, Baseline, n=155, 155 | 4.96 (± 1.519) | 5.10 (± 1.510) | | |
| NNRTI, Urea, Week 4, n=151, 153 | 5.08 (± 1.556) | 5.09 (± 1.426) | | |
| NNRTI, Urea, Week 8, n=122, 152 | 5.09 (± 1.675) | 5.10 (± 1.465) | | |
| NNRTI, Urea, Week 12, n=146, 152 | 5.20 (± 1.684) | 5.13 (± 1.583) | | |
| NNRTI, Urea, Week 16, n=143, 149 | 5.03 (± 1.768) | 5.34 (± 1.660) | | |
| NNRTI, Urea, Week 20, n=138, 152 | 5.18 (± 1.709) | 5.15 (± 1.713) | | |
| NNRTI, Urea, Week 24, n=143, 151 | 5.29 (± 1.878) | 5.26 (± 1.591) | | |
| NNRTI, Urea, Week 28, n=136, 150 | 5.20 (± 1.931) | 5.10 (± 1.537) | | |
| NNRTI, Urea, Week 32, n=137, 148 | 5.38 (± 1.796) | 5.14 (± 1.687) | | |
| NNRTI, Urea, Week 36, n=135, 147 | 5.07 (± 1.719) | 5.13 (± 1.493) | | |
| NNRTI, Urea, Week 40, n=138, 147 | 5.30 (± 1.616) | 5.07 (± 1.377) | | |
| NNRTI, Urea, Week 44, n=137, 148 | 5.23 (± 1.489) | 5.18 (± 1.613) | | |
| NNRTI, Urea, Week 48, n=131, 147 | 5.32 (± 1.671) | 5.06 (± 1.380) | | |

Notes:

[107] - Safety Population

[108] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values for fasting lipid panel using baseline third agent treatment class overtime including Week 48

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| End point title | Absolute values for fasting lipid panel using baseline third agent treatment class overtime including Week 48 |
| End point description: | |
| Blood samples were collected for the analysis of fasting lipid panel: triglycerides, total cholesterol, HDL cholesterol and LDL cholesterol to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles). | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Day 1) and at Week 48 | |

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[109] | 308 ^[110] | | |
| Units: Millimoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Triglycerides, Baseline, n=46, 50 | 1.951 (± 1.8801) | 1.894 (± 1.4058) | | |
| PI, Triglycerides, Week 48, n=40, 45 | 1.309 (± 0.7647) | 1.772 (± 1.1828) | | |
| INI, Triglycerides, Baseline, n=82, 84 | 1.470 (± 1.0152) | 1.426 (± 0.8720) | | |
| INI, Triglycerides, Week 48, n=72, 77 | 1.405 (± 0.9068) | 1.307 (± 0.7427) | | |
| NNRTI, Triglycerides, Baseline, n=136, 140 | 1.322 (± 0.7986) | 1.506 (± 1.4388) | | |
| NNRTI, Triglycerides, Week 48, n=119, 120 | 1.305 (± 0.8771) | 1.316 (± 0.7914) | | |
| PI, Cholesterol, Baseline, n=46, 50 | 4.98 (± 0.960) | 5.14 (± 1.152) | | |
| PI, Cholesterol, Week 48, n=40, 45 | 5.07 (± 0.775) | 5.16 (± 1.130) | | |
| INI, Cholesterol, Baseline, n=82, 84 | 4.81 (± 1.077) | 5.01 (± 1.080) | | |
| INI, Cholesterol, Week 48, n=72, 77 | 4.90 (± 0.881) | 4.87 (± 0.997) | | |
| NNRTI, Cholesterol, Baseline, n=136, 140 | 4.87 (± 0.958) | 4.98 (± 1.007) | | |
| NNRTI, Cholesterol, Week 48, n=119, 120 | 4.93 (± 0.904) | 4.91 (± 1.007) | | |
| PI, HDL cholesterol, Baseline, n=46, 50 | 1.389 (± 0.4943) | 1.537 (± 0.6096) | | |
| PI, HDL cholesterol, Week 48, n=40, 45 | 1.505 (± 0.5459) | 1.550 (± 0.5950) | | |
| INI, HDL cholesterol, Baseline, n=82, 84 | 1.257 (± 0.3450) | 1.383 (± 0.3890) | | |
| INI, HDL cholesterol, Week 48, n=72, 77 | 1.288 (± 0.3664) | 1.323 (± 0.3588) | | |
| NNRTI, HDL cholesterol, Baseline, n=136, 140 | 1.449 (± 0.4756) | 1.405 (± 0.4401) | | |
| NNRTI, HDL cholesterol, Week 48, n=119, 120 | 1.442 (± 0.4413) | 1.471 (± 0.4226) | | |
| PI, LDL cholesterol, Baseline, n=43, 48 | 2.734 (± 0.7891) | 2.743 (± 0.7948) | | |
| PI, LDL cholesterol, Week 48, n=37, 43 | 2.944 (± 0.7175) | 2.784 (± 0.8477) | | |
| INI, LDL cholesterol, Baseline, n=81, 83 | 2.881 (± 0.9196) | 2.946 (± 0.8614) | | |
| INI, LDL cholesterol, Week 48, n=71, 76 | 2.975 (± 0.8787) | 2.939 (± 0.8591) | | |
| NNRTI, LDL cholesterol, Baseline, n=134, 137 | 2.834 (± 0.8442) | 2.901 (± 0.8714) | | |
| NNRTI, LDL cholesterol, Week 48, n=116, 119 | 2.900 (± 0.8415) | 2.834 (± 0.8763) | | |

Notes:

[109] - Safety Population

[110] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants discontinued or withdrawn due to AEs when

Baseline third agent treatment class was used over time including Week 48

| | |
|-----------------|--|
| End point title | Number of participants discontinued or withdrawn due to AEs when Baseline third agent treatment class was used over time including Week 48 |
|-----------------|--|

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment.

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

End point timeframe:

Up to Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[111] | 308 ^[112] | | |
| Units: Participants | | | | |
| PI | 2 | 2 | | |
| INI | 6 | 0 | | |
| NNRTI | 5 | 3 | | |

Notes:

[111] - Safety Population

[112] - Safety Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|-----------------|---|
| End point title | Plasma trough concentration (Ctough) for CAB LA evaluable |
|-----------------|---|

End point description:

Blood samples will be collected at indicated time points for pharmacokinetic (PK) analysis of CAB LA. PK population includes all participants who received CAB and / or RPV and underwent PK sampling during the study, and provided CAB and /or RPV plasma concentration data. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA | | | |
|--|---------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 308 ^[113] | | | |
| Units: Micrograms per milliliter | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Pre-dose, Week 8, n=252 | 1.2277 (1.1293 to 1.3346) | | | |

| | | | | |
|--------------------------|---------------------------|--|--|--|
| Pre-dose, Week 12, n=261 | 1.6925 (1.6005 to 1.7897) | | | |
| Pre-dose, Week 16, n=248 | 1.9533 (1.8492 to 2.0632) | | | |
| Pre-dose, Week 20, n=233 | 2.1036 (1.9924 to 2.2209) | | | |
| Pre-dose, Week 24, n=234 | 2.2537 (2.1177 to 2.3984) | | | |
| Pre-dose, Week 28, n=232 | 2.4300 (2.3093 to 2.5569) | | | |
| Pre-dose, Week 32, n=219 | 2.4483 (2.3321 to 2.5703) | | | |
| Pre-dose, Week 36, n=209 | 2.4681 (2.3377 to 2.6057) | | | |
| Pre-dose, Week 40, n=209 | 2.5126 (2.3477 to 2.6890) | | | |
| Pre-dose, Week 44, n=221 | 2.7748 (2.6323 to 2.9250) | | | |
| Pre-dose, Week 48, n=217 | 2.8378 (2.6763 to 3.0090) | | | |

Notes:

[113] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough for RPV LA evaluable

| | |
|-----------------|------------------------------|
| End point title | Ctrough for RPV LA evaluable |
|-----------------|------------------------------|

End point description:

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

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

End point timeframe:

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

| End point values | RPV LA | | | |
|--|------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 308 ^[114] | | | |
| Units: Nanograms per milliliter | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Pre-dose, Week 8, n=251 | 38.58 (35.96 to 41.39) | | | |

| | | | | |
|--------------------------|------------------------|--|--|--|
| Pre-dose, Week 12, n=261 | 47.00 (44.50 to 49.64) | | | |
| Pre-dose, Week 16, n=247 | 53.87 (50.92 to 56.98) | | | |
| Pre-dose, Week 20, n=233 | 54.14 (51.13 to 57.34) | | | |
| Pre-dose, Week 24, n=231 | 61.26 (57.80 to 64.93) | | | |
| Pre-dose, Week 28, n=232 | 66.53 (62.87 to 70.40) | | | |
| Pre-dose, Week 32, n=218 | 70.93 (66.97 to 75.11) | | | |
| Pre-dose, Week 36, n=209 | 73.00 (68.54 to 77.75) | | | |
| Pre-dose, Week 40, n=208 | 76.24 (71.71 to 81.07) | | | |
| Pre-dose, Week 44, n=223 | 83.65 (78.94 to 88.63) | | | |
| Pre-dose, Week 48, n=216 | 90.28 (84.92 to 95.98) | | | |

Notes:

[114] - PK Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|-----------------|--|
| End point title | Area under the curve (AUC) for CAB LA and RPV LA evaluable |
|-----------------|--|

End point description:

Blood samples were collected at indicated time points to analyse AUC concentration in plasma for CAB LA. 99999 indicates data was not available due to sparse sampling post IM dosing.

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

End point timeframe:

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

| End point values | CAB LA | RPV LA | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 308 ^[115] | 308 ^[116] | | |
| Units: Hours*microgram per milliliter | | | | |
| geometric mean (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Notes:

[115] - PK Population

[116] - PK Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|---|--|
| End point title | Maximum concentration (Cmax) in plasma for CAB LA evaluable at Week 41 |
| End point description: Blood samples will be collected at indicated time points for PK analysis of CAB LA. Only those participants with data available at the specified data points were analyzed. | |
| End point type | Secondary |
| End point timeframe: Week 41- 1 Week post dose | |

| End point values | CAB LA | | | |
|--|---------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 251 ^[117] | | | |
| Units: Micrograms per milliliter | | | | |
| geometric mean (confidence interval 95%) | 3.3862 (3.1804 to 3.6054) | | | |

Notes:

[117] - PK Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|---|--|
| End point title | Cmax in plasma for RPV LA evaluable at Week 41 |
| End point description: Blood samples will be collected at indicated time points for PK analysis of RPV LA. Only those participants with data available at the specified data points were analyzed. | |
| End point type | Secondary |
| End point timeframe: Week 41- 1 Week post dose | |

| End point values | RPV LA | | | |
|--|---------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 251 ^[118] | | | |
| Units: Nanograms per milliliter | | | | |
| geometric mean (confidence interval 95%) | 110.36 (103.28 to 117.93) | | | |

Notes:

[118] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a virologic failure using snapshot algorithm by Baseline third agent

| | |
|-----------------|--|
| End point title | Percentage of participants with a virologic failure using snapshot algorithm by Baseline third agent |
|-----------------|--|

End point description:

Percentage of participants with virologic failure endpoint as per FDA snapshot algorithm at Week 48 was assessed based on the non-inferior antiviral activity of switching IM CAB LA+RPV LA every 4 weeks compared to continuation of current ART regimen over 48 weeks in HIV-1 infected ART-experienced participants. The HIV-RNA ≥ 50 copies/mL per snapshot algorithm was determined using a Cochran-Mantel Haenszel test stratified by baseline third agent class: INI, NNRTI, or PI. 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 (Q4W) | Current ART | | |
|-----------------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[119] | 308 ^[120] | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| PI, n=51, 54 | 2.0 | 0 | | |
| INI, n=102, 99 | 0 | 2.0 | | |
| NNRTI, n=155, 155 | 2.6 | 0.6 | | |

Notes:

[119] - ITT-E Population.

[120] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <50copies/mL using snapshot algorithm by Baseline third agent

| | |
|-----------------|--|
| End point title | Percentage of participants with plasma HIV-1 RNA <50copies/mL using snapshot algorithm by Baseline third agent |
|-----------------|--|

End point description:

Percentage of participants with HIV-1 RNA < 50copies/mL endpoint as per FDA snapshot algorithm at Week 48 was assessed based on the non-inferior antiviral activity of switching IM CAB LA+RPV LA every 4 weeks compared to continuation of current ART regimen over 48 weeks in HIV-1 infected ART-experienced participants. The HIV-RNA <50 copies/mL per snapshot algorithm was determined using a Cochran-Mantel Haenszel test stratified by baseline third agent class: INI, NNRTI, or PI. 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 (Q4W) | Current ART | | |
|-----------------------------------|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[121] | 308 ^[122] | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| PI, n=51, 54 | 92 | 94 | | |
| INI, n=102, 99 | 94 | 96 | | |
| NNRTI, n=155, 155 | 92 | 95 | | |

Notes:

[121] - ITT-E Population

[122] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with severity of adverse events by Baseline third agents

| | |
|-----------------|---|
| End point title | Number of participants with severity of adverse events by Baseline third agents |
|-----------------|---|

End point description:

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

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

End point timeframe:

Up to Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|-----------------------------|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[123] | 308 ^[124] | | |
| Units: Participants | | | | |
| PI, Grade 1 | 22 | 20 | | |
| PI, Grade 2 | 20 | 11 | | |
| PI, Grade 3 | 4 | 4 | | |
| PI, Grade 4 | 1 | 0 | | |
| PI, Grade 5 | 0 | 1 | | |
| INI, Grade 1 | 40 | 40 | | |
| INI, Grade 2 | 50 | 23 | | |
| INI, Grade 3 | 8 | 3 | | |
| INI, Grade 4 | 1 | 2 | | |
| INI, Grade 5 | 0 | 0 | | |
| NNRTI, Grade 1 | 39 | 55 | | |
| NNRTI, Grade 2 | 88 | 47 | | |
| NNRTI, Grade 3 | 15 | 12 | | |
| NNRTI, Grade 4 | 6 | 2 | | |
| NNRTI, Grade 5 | 0 | 0 | | |

Notes:

[123] - Safety Population

[124] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: ALT, ALP, AST and CK

| | |
|-----------------|---|
| End point title | Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: ALT, ALP, AST and CK |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: ALT, ALP, AST and CK to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[125] | 308 ^[126] | | |
| Units: International units per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, ALT, Week 4, n=51, 53 | 9.4 (± 17.93) | 1.1 (± 9.99) | | |
| PI, ALT, Week 8, n=34, 53 | 7.9 (± 17.19) | 0.9 (± 7.20) | | |
| PI, ALT, Week 12, n=50, 52 | 5.3 (± 17.31) | 1.4 (± 9.76) | | |
| PI, ALT, Week 16, n=48, 53 | 6.5 (± 20.92) | 1.4 (± 8.75) | | |
| PI, ALT, Week 20, n=46, 53 | 4.9 (± 18.06) | 0.3 (± 7.34) | | |
| PI, ALT, Week 24, n=47, 53 | 4.1 (± 14.42) | 0.5 (± 7.30) | | |
| PI, ALT, Week 28, n=42, 53 | 2.6 (± 11.47) | 0.8 (± 7.46) | | |
| PI, ALT, Week 32, n=45, 51 | 3.5 (± 14.88) | 0.5 (± 7.36) | | |
| PI, ALT, Week 36, n=44, 50 | 3.3 (± 13.55) | 2.0 (± 9.78) | | |
| PI, ALT, Week 40, n=42, 51 | 5.4 (± 17.81) | 1.1 (± 10.52) | | |
| PI, ALT, Week 44, n=47, 51 | 4.0 (± 15.83) | 0.9 (± 11.97) | | |
| PI, ALT, Week 48, n=43, 50 | 2.9 (± 10.69) | 0.5 (± 8.04) | | |
| INI, ALT, Week 4, n=99, 97 | 1.7 (± 15.15) | 0.7 (± 7.20) | | |
| INI, ALT, Week 8, n=73, 98 | 3.3 (± 18.20) | 5.4 (± 50.20) | | |
| INI, ALT, Week 12, n=99, 95 | -1.0 (± 12.48) | 1.7 (± 10.63) | | |
| INI, ALT, Week 16, n=93, 96 | -1.8 (± 12.27) | -0.1 (± 8.58) | | |
| INI, ALT, Week 20, n=93, 97 | -1.9 (± 13.60) | -0.5 (± 9.38) | | |
| INI, ALT, Week 24, n=94, 95 | 0.6 (± 17.33) | 0.1 (± 9.95) | | |
| INI, ALT, Week 28, n=89, 93 | -2.4 (± 9.70) | -0.4 (± 12.31) | | |

| | | | | |
|---------------------------------|-----------------|----------------|--|--|
| INI, ALT, Week 32, n=93, 95 | -1.8 (± 12.87) | -0.3 (± 7.79) | | |
| INI, ALT, Week 36, n=94, 95 | 1.5 (± 35.82) | -0.4 (± 8.79) | | |
| INI, ALT, Week 40, n=90, 95 | 5.0 (± 59.10) | -0.6 (± 9.62) | | |
| INI, ALT, Week 44, n=91, 94 | -1.6 (± 13.90) | -0.4 (± 7.91) | | |
| INI, ALT, Week 48, n=91, 95 | -0.2 (± 15.17) | -0.8 (± 7.41) | | |
| NNRTI, ALT, Week 4, n=151, 153 | -2.6 (± 9.82) | -0.7 (± 10.80) | | |
| NNRTI, ALT, Week 8, n=122, 152 | -2.9 (± 11.62) | -0.8 (± 12.06) | | |
| NNRTI, ALT, Week 12, n=146, 152 | 9.5 (± 160.61) | -0.8 (± 12.66) | | |
| NNRTI, ALT, Week 16, n=143, 149 | -1.3 (± 26.21) | -1.6 (± 11.39) | | |
| NNRTI, ALT, Week 20, n=138, 152 | -2.0 (± 28.04) | -2.0 (± 12.61) | | |
| NNRTI, ALT, Week 24, n=143, 151 | 2.6 (± 85.48) | -1.3 (± 11.85) | | |
| NNRTI, ALT, Week 28, n=136, 150 | -4.5 (± 11.46) | -0.5 (± 14.03) | | |
| NNRTI, ALT, Week 32, n=137, 148 | -3.8 (± 14.93) | -0.9 (± 14.33) | | |
| NNRTI, ALT, Week 36, n=135, 147 | -3.8 (± 12.44) | -0.1 (± 12.48) | | |
| NNRTI, ALT, Week 40, n=138, 147 | -3.8 (± 13.48) | -0.4 (± 13.47) | | |
| NNRTI, ALT, Week 44, n=137, 148 | -4.7 (± 12.67) | -0.4 (± 14.67) | | |
| NNRTI, ALT, Week 48, n=131, 147 | -4.6 (± 12.38) | -0.9 (± 12.75) | | |
| PI, ALP, Week 4, n=51, 53 | -3.5 (± 11.63) | -2.9 (± 8.07) | | |
| PI, ALP, Week 8, n=34, 53 | -2.1 (± 24.59) | 0.2 (± 11.37) | | |
| PI, ALP, Week 12, n=50, 52 | -5.7 (± 14.40) | 0.9 (± 10.22) | | |
| PI, ALP, Week 16, n=48, 53 | -7.3 (± 17.09) | 0.6 (± 8.68) | | |
| PI, ALP, Week 20, n=46, 53 | -6.8 (± 16.71) | 0.1 (± 10.70) | | |
| PI, ALP, Week 24, n=47, 53 | -7.5 (± 17.90) | -0.4 (± 7.67) | | |
| PI, ALP, Week 28, n=42, 53 | -7.3 (± 17.23) | 3.0 (± 9.69) | | |
| PI, ALP, Week 32, n=45, 51 | -9.3 (± 16.47) | -0.7 (± 8.50) | | |
| PI, ALP, Week 36, n=44, 50 | -10.2 (± 18.52) | 0.6 (± 13.52) | | |
| PI, ALP, Week 40, n=42, 51 | -8.7 (± 17.37) | -1.4 (± 8.79) | | |
| PI, ALP, Week 44, n=47, 51 | -11.5 (± 17.49) | -0.9 (± 9.05) | | |
| PI, ALP, Week 48, n=43, 50 | -8.0 (± 16.05) | -0.2 (± 9.08) | | |
| INI, ALP, Week 4, n=99, 97 | -0.5 (± 10.59) | -0.9 (± 7.92) | | |
| INI, ALP, Week 8, n=73, 98 | -1.8 (± 8.55) | 4.9 (± 33.17) | | |
| INI, ALP, Week 12, n=99, 95 | -1.6 (± 8.57) | 3.5 (± 19.97) | | |
| INI, ALP, Week 16, n=93, 96 | -1.7 (± 10.53) | -0.2 (± 10.93) | | |
| INI, ALP, Week 20, n=93, 97 | -2.0 (± 10.23) | -0.4 (± 7.93) | | |
| INI, ALP, Week 24, n=94, 95 | -1.4 (± 10.23) | -0.6 (± 8.25) | | |
| INI, ALP, Week 28, n=89, 93 | -2.1 (± 10.83) | -0.8 (± 8.80) | | |
| INI, ALP, Week 32, n=93, 95 | -1.6 (± 11.08) | -2.0 (± 8.23) | | |
| INI, ALP, Week 36, n=94, 95 | -2.4 (± 12.03) | -2.2 (± 9.41) | | |
| INI, ALP, Week 40, n=90, 95 | -0.9 (± 13.77) | -1.9 (± 9.33) | | |
| INI, ALP, Week 44, n=91, 94 | -2.6 (± 13.69) | -0.4 (± 11.60) | | |
| INI, ALP, Week 48, n=91, 95 | -1.9 (± 13.29) | -1.2 (± 10.26) | | |
| NNRTI, ALP, Week 4, n=151, 153 | -10.4 (± 12.81) | -2.7 (± 9.60) | | |
| NNRTI, ALP, Week 8, n=122, 152 | -10.9 (± 16.50) | -1.0 (± 10.77) | | |
| NNRTI, ALP, Week 12, n=146, 152 | -13.0 (± 26.62) | -0.7 (± 11.04) | | |
| NNRTI, ALP, Week 16, n=143, 149 | -15.7 (± 22.52) | -1.0 (± 10.54) | | |
| NNRTI, ALP, Week 20, n=138, 152 | -14.9 (± 22.35) | -1.8 (± 13.77) | | |

| | | | | |
|---------------------------------|-----------------|------------------|--|--|
| NNRTI, ALP, Week 24, n=143, 151 | -14.5 (± 21.88) | 0.4 (± 12.75) | | |
| NNRTI, ALP, Week 28, n=136, 150 | -16.2 (± 21.66) | -1.0 (± 13.18) | | |
| NNRTI, ALP, Week 32, n=137, 148 | -15.8 (± 21.98) | -1.8 (± 13.63) | | |
| NNRTI, ALP, Week 36, n=135, 147 | -16.1 (± 23.60) | -1.0 (± 11.86) | | |
| NNRTI, ALP, Week 40, n=138, 147 | -17.2 (± 22.83) | -0.4 (± 13.19) | | |
| NNRTI, ALP, Week 44, n=137, 148 | -17.3 (± 23.32) | -0.8 (± 13.20) | | |
| NNRTI, ALP, Week 48, n=131, 147 | -18.0 (± 27.97) | 0.2 (± 14.69) | | |
| PI, AST, Week 4, n=51, 53 | 3.8 (± 9.18) | 2.3 (± 16.78) | | |
| PI, AST, Week 8, n=34, 53 | 5.1 (± 8.35) | -0.1 (± 4.60) | | |
| PI, AST, Week 12, n=50, 52 | 2.7 (± 11.49) | 1.7 (± 7.21) | | |
| PI, AST, Week 16, n=48, 53 | 3.9 (± 16.81) | 1.8 (± 10.69) | | |
| PI, AST, Week 20, n=46, 53 | 4.1 (± 20.85) | 0.5 (± 4.29) | | |
| PI, AST, Week 24, n=47, 53 | 1.5 (± 7.76) | 1.6 (± 9.93) | | |
| PI, AST, Week 28, n=42, 53 | 2.9 (± 8.86) | 1.9 (± 7.45) | | |
| PI, AST, Week 32, n=45, 51 | 3.1 (± 14.13) | 0.6 (± 4.93) | | |
| PI, AST, Week 36, n=44, 50 | 1.7 (± 8.04) | 1.9 (± 6.24) | | |
| PI, AST, Week 40, n=42, 51 | 5.7 (± 24.61) | 0.5 (± 6.05) | | |
| PI, AST, Week 44, n=47, 51 | 1.7 (± 9.71) | 1.4 (± 11.60) | | |
| PI, AST, Week 48, n=43, 50 | 1.7 (± 7.09) | 2.1 (± 8.74) | | |
| INI, AST, Week 4, n=99, 97 | 0.0 (± 15.36) | -0.1 (± 6.29) | | |
| INI, AST, Week 8, n=73, 98 | 3.3 (± 25.01) | 1.2 (± 21.48) | | |
| INI, AST, Week 12, n=99, 95 | -1.3 (± 14.22) | 0.8 (± 7.35) | | |
| INI, AST, Week 16, n=93, 96 | -2.1 (± 12.73) | 0.1 (± 10.96) | | |
| INI, AST, Week 20, n=93, 97 | -1.7 (± 13.77) | -0.9 (± 12.67) | | |
| INI, AST, Week 24, n=94, 95 | -0.4 (± 14.88) | -0.2 (± 10.40) | | |
| INI, AST, Week 28, n=89, 93 | -1.4 (± 7.74) | -0.9 (± 13.48) | | |
| INI, AST, Week 32, n=93, 95 | -2.1 (± 13.06) | -0.8 (± 10.01) | | |
| INI, AST, Week 36, n=94, 95 | -0.7 (± 17.34) | -1.1 (± 11.70) | | |
| INI, AST, Week 40, n=90, 95 | 1.0 (± 20.11) | -0.4 (± 13.96) | | |
| INI, AST, Week 44, n=91, 94 | 1.0 (± 24.54) | -0.7 (± 10.69) | | |
| INI, AST, Week 48, n=91, 95 | 0.4 (± 16.57) | 0.2 (± 11.91) | | |
| NNRTI, AST, Week 4, n=151, 153 | -1.9 (± 11.09) | -0.5 (± 8.73) | | |
| NNRTI, AST, Week 8, n=122, 152 | -1.3 (± 18.14) | -0.9 (± 8.31) | | |
| NNRTI, AST, Week 12, n=146, 152 | 4.7 (± 91.54) | 0.0 (± 10.08) | | |
| NNRTI, AST, Week 16, n=143, 149 | 0.3 (± 21.80) | -1.0 (± 8.37) | | |
| NNRTI, AST, Week 20, n=138, 152 | -1.2 (± 17.47) | -0.7 (± 9.09) | | |
| NNRTI, AST, Week 24, n=143, 150 | -0.1 (± 31.53) | -0.4 (± 8.87) | | |
| NNRTI, AST, Week 28, n=136, 150 | -2.8 (± 9.02) | 0.4 (± 10.70) | | |
| NNRTI, AST, Week 32, n=137, 148 | -2.0 (± 18.27) | 1.5 (± 16.84) | | |
| NNRTI, AST, Week 36, n=135, 147 | -2.5 (± 10.33) | 0.2 (± 9.00) | | |
| NNRTI, AST, Week 40, n=138, 147 | -2.7 (± 11.14) | 0.1 (± 9.40) | | |
| NNRTI, AST, Week 44, n=137, 148 | -3.4 (± 10.38) | 0.1 (± 11.20) | | |
| NNRTI, AST, Week 48, n=131, 147 | -2.9 (± 10.87) | 0.5 (± 10.60) | | |
| PI, CK, Week 4, n=51, 53 | 8.6 (± 182.21) | 133.5 (± 907.82) | | |
| PI, CK, Week 8, n=34, 53 | 67.9 (± 176.14) | 23.5 (± 174.40) | | |

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| PI, CK, Week 12, n=50, 52 | 3.1 (± 162.71) | 57.9 (± 406.52) | | |
| PI, CK, Week 16, n=48, 53 | 19.4 (± 253.86) | 16.3 (± 66.34) | | |
| PI, CK, Week 20, n=46, 53 | 103.6 (± 696.54) | 6.8 (± 72.86) | | |
| PI, CK, Week 24, n=47, 53 | -3.0 (± 181.03) | 18.2 (± 86.69) | | |
| PI, CK, Week 28, n=42, 53 | 60.3 (± 299.83) | 13.5 (± 93.14) | | |
| PI, CK, Week 32, n=45, 51 | 157.1 (± 988.65) | 1.5 (± 64.94) | | |
| PI, CK, Week 36, n=44, 50 | -9.0 (± 191.25) | 22.3 (± 62.09) | | |
| PI, CK, Week 40, n=42, 51 | 193.7 (± 1188.89) | 0.3 (± 48.24) | | |
| PI, CK, Week 44, n=47, 51 | -6.3 (± 185.69) | 4.8 (± 62.91) | | |
| PI, CK, Week 48, n=43, 50 | -1.0 (± 158.33) | 72.9 (± 478.94) | | |
| INI, CK, Week 4, n=99, 97 | -32.7 (± 717.86) | -17.9 (± 260.84) | | |
| INI, CK, Week 8, n=73, 98 | 95.6 (± 801.75) | -58.0 (± 577.11) | | |
| INI, CK, Week 12, n=99, 95 | -16.1 (± 852.44) | -23.9 (± 304.61) | | |
| INI, CK, Week 16, n=93, 96 | -59.5 (± 629.54) | -1.9 (± 686.38) | | |
| INI, CK, Week 20, n=93, 97 | -55.7 (± 623.92) | -58.1 (± 622.84) | | |
| INI, CK, Week 24, n=94, 95 | -63.1 (± 549.02) | -40.7 (± 588.24) | | |
| INI, CK Week 28, n=89, 93 | -17.4 (± 224.35) | -27.4 (± 759.07) | | |
| INI, CK, Week 32, n=93, 95 | -82.8 (± 587.51) | -42.1 (± 637.00) | | |
| INI, CK, Week 36, n=94, 95 | -76.1 (± 602.03) | -60.9 (± 603.48) | | |
| INI, CK, Week 40, n=90, 95 | 40.3 (± 864.00) | -36.2 (± 609.80) | | |
| INI, CK, Week 44, n=91, 94 | 199.8 (± 2043.35) | -60.2 (± 576.84) | | |
| INI, CK, Week 48, n=91, 95 | 20.5 (± 861.55) | -25.0 (± 653.03) | | |
| NNRTI, CK, Week 4, n=151, 153 | 18.2 (± 502.12) | 26.0 (± 214.58) | | |
| NNRTI, CK, Week 8, n=122, 152 | 108.2 (± 1339.52) | -3.6 (± 108.28) | | |
| NNRTI, CK, Week 12, n=146, 152 | 21.9 (± 440.81) | 24.5 (± 222.26) | | |
| NNRTI, CK, Week 16, n=143, 149 | 139.9 (± 1121.08) | 7.0 (± 189.21) | | |
| NNRTI, CK, Week 20, n=138, 152 | 65.5 (± 656.11) | 1.6 (± 114.05) | | |
| NNRTI, CK, Week 24, n=143, 151 | 24.1 (± 606.47) | 17.7 (± 167.38) | | |
| NNRTI, CK, Week 28, n=136, 150 | -10.9 (± 169.29) | 53.2 (± 462.07) | | |
| NNRTI, CK, Week 32, n=137, 148 | 31.3 (± 650.27) | 94.0 (± 665.17) | | |
| NNRTI, CK, Week 36, n=135, 147 | 19.0 (± 440.56) | 10.3 (± 135.08) | | |

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| NNRTI, CK, Week 40, n=138, 147 | -7.7 (± 237.00) | 22.6 (± 195.23) | | |
| NNRTI, CK, Week 44, n=137, 148 | -35.4 (± 183.15) | 14.9 (± 173.39) | | |
| NNRTI, CK, Week 48, n=131, 147 | -15.1 (± 212.52) | 27.3 (± 272.59) | | |

Notes:

[125] - Safety Population

[126] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Albumin

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| End point title | Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Albumin |
|-----------------|--|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: albumin to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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| End point type | Secondary |
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End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[127] | 308 ^[128] | | |
| Units: Grams per Liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Week 4, n=51, 53 | 0.2 (± 2.21) | -0.2 (± 2.41) | | |
| PI, Week 8, n=34, 53 | 0.7 (± 2.73) | -0.1 (± 2.74) | | |
| PI, Week 12, n=50, 52 | -0.2 (± 2.67) | -0.3 (± 2.81) | | |
| PI, Week 16, n=48, 53 | -0.2 (± 2.77) | -0.8 (± 2.72) | | |
| PI, Week 20, n=46, 53 | -0.4 (± 2.35) | -0.8 (± 2.82) | | |
| PI, Week 24, n=47, 53 | -0.6 (± 2.24) | -0.8 (± 2.40) | | |
| PI, Week 28, n=42, 53 | -0.6 (± 2.26) | -1.4 (± 2.08) | | |
| PI, Week 32, n=45, 51 | -0.7 (± 2.39) | -0.5 (± 2.42) | | |
| PI, Week 36, n=44, 50 | -0.6 (± 2.44) | -0.9 (± 2.48) | | |
| PI, Week 40, n=42, 51 | -0.1 (± 2.72) | -0.5 (± 2.37) | | |
| PI, Week 44, n=47, 51 | -0.5 (± 2.15) | -0.5 (± 2.60) | | |
| PI, Week 48, n=43, 50 | -0.3 (± 2.74) | -0.1 (± 2.44) | | |
| INI, Week 4, n=99, 97 | -0.4 (± 2.56) | -0.9 (± 2.62) | | |
| INI, Week 8, n=73, 98 | -0.5 (± 2.59) | -1.0 (± 2.89) | | |
| INI, Week 12, n=99, 95 | -0.3 (± 2.92) | -0.5 (± 2.59) | | |
| INI, Week 16, n=93, 96 | -0.5 (± 2.78) | -1.1 (± 2.80) | | |
| INI, Week 20, n=93, 97 | -0.7 (± 2.71) | -0.7 (± 2.77) | | |

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| INI, Week 24, n=94, 95 | -0.8 (± 2.86) | -1.0 (± 2.74) | | |
| INI, Week 28, n=89, 93 | -0.3 (± 2.55) | -1.1 (± 2.87) | | |
| INI, Week 32, n=93, 95 | -0.2 (± 2.70) | -1.3 (± 2.77) | | |
| INI, Week 36, n=94, 95 | -0.8 (± 2.67) | -1.1 (± 2.54) | | |
| INI, Week 40, n=90, 95 | -0.3 (± 2.40) | -1.3 (± 2.84) | | |
| INI, Week 44, n=91, 94 | -0.5 (± 2.77) | -1.0 (± 2.76) | | |
| INI, Week 48, n=91, 95 | -0.1 (± 2.69) | -0.5 (± 2.69) | | |
| NNRTI, Week 4, n=151, 153 | -0.8 (± 2.70) | -0.3 (± 2.42) | | |
| NNRTI, Week 8, n=122, 152 | -0.4 (± 2.83) | -0.6 (± 2.53) | | |
| NNRTI, Week 12, n=146, 152 | -0.8 (± 2.59) | -0.3 (± 2.61) | | |
| NNRTI, Week 16, n=143, 149 | -0.8 (± 2.79) | -0.7 (± 2.63) | | |
| NNRTI, Week 20, n=138, 152 | -0.9 (± 2.96) | -0.9 (± 2.33) | | |
| NNRTI, Week 24, n=143, 151 | -0.7 (± 2.73) | -0.7 (± 2.57) | | |
| NNRTI, Week 28, n=136, 150 | -0.9 (± 2.72) | -0.9 (± 2.34) | | |
| NNRTI, Week 32, n=137, 148 | -0.9 (± 2.94) | -1.0 (± 2.45) | | |
| NNRTI, Week 36, n=135, 147 | -1.0 (± 2.83) | -0.8 (± 2.79) | | |
| NNRTI, Week 40, n=138, 147 | -0.7 (± 2.54) | -1.0 (± 2.52) | | |
| NNRTI, Week 44, n=137, 148 | -0.3 (± 2.60) | -0.8 (± 2.22) | | |
| NNRTI, Week 48, n=131, 147 | -0.6 (± 2.57) | -0.5 (± 2.49) | | |

Notes:

[127] - Safety Population

[128] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Bilirubin, direct bilirubin and creatinine

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| End point title | Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Bilirubin, direct bilirubin and creatinine |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: bilirubin, direct bilirubin and creatinine to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[129] | 308 ^[130] | | |
| Units: Micromoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Bilirubin, Week 4, n=51, 53 | -9.0 (± 20.62) | 0.3 (± 6.95) | | |
| PI, Bilirubin, Week 8, n=34, 53 | -6.6 (± 13.76) | 0.1 (± 5.76) | | |

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| PI, Bilirubin, Week 12, n=50, 52 | -10.2 (± 20.18) | 1.7 (± 7.11) | | |
| PI, Bilirubin, Week 16, n=48, 53 | -10.0 (± 20.13) | 0.6 (± 6.42) | | |
| PI, Bilirubin, Week 20, n=46, 53 | -9.2 (± 20.21) | 1.5 (± 12.45) | | |
| PI, Bilirubin, Week 24, n=47, 53 | -9.6 (± 20.64) | 2.7 (± 11.87) | | |
| PI, Bilirubin, Week 28, n=42, 53 | -10.0 (± 22.42) | 0.9 (± 7.70) | | |
| PI, Bilirubin, Week 32, n=45, 51 | -8.9 (± 21.34) | 2.7 (± 8.64) | | |
| PI, Bilirubin, Week 36, n=44, 50 | -10.5 (± 21.75) | 2.6 (± 7.35) | | |
| PI, Bilirubin, Week 40, n=42, 51 | -11.0 (± 22.20) | 3.5 (± 12.74) | | |
| PI, Bilirubin, Week 44, n=47, 51 | -9.6 (± 20.32) | 3.7 (± 9.10) | | |
| PI, Bilirubin, Week 48, n=43, 50 | -10.7 (± 21.77) | 2.3 (± 5.23) | | |
| INI, Bilirubin, Week 4, n=99, 97 | 0.2 (± 3.92) | -0.7 (± 3.93) | | |
| INI, Bilirubin, Week 8, n=73, 98 | 0.4 (± 3.96) | 0.9 (± 12.43) | | |
| INI, Bilirubin, Week 12, n=99, 95 | 0.6 (± 4.41) | -0.5 (± 4.69) | | |
| INI, Bilirubin, Week 16, n=93, 96 | 0.6 (± 4.30) | -0.2 (± 4.35) | | |
| INI, Bilirubin, Week 20, n=93, 97 | 0.9 (± 4.08) | -0.5 (± 4.32) | | |
| INI, Bilirubin, Week 24, n=94, 94 | 0.2 (± 3.72) | -0.5 (± 3.88) | | |
| INI, Bilirubin, Week 28, n=89, 93 | 1.1 (± 3.58) | -0.4 (± 4.85) | | |
| INI, Bilirubin, Week 32, n=93, 95 | 0.7 (± 4.67) | -1.1 (± 4.54) | | |
| INI, Bilirubin, Week 36, n=94, 95 | 0.5 (± 4.07) | -0.6 (± 4.62) | | |
| INI, Bilirubin, Week 40, n=90, 95 | 0.6 (± 4.28) | -1.0 (± 4.26) | | |
| INI, Bilirubin, Week 44, n=91, 94 | 0.9 (± 4.34) | -0.7 (± 4.72) | | |
| INI, Bilirubin, Week 48, n=91, 95 | 1.1 (± 3.72) | -0.9 (± 3.96) | | |
| NNRTI, Bilirubin, Week 4, n=151, 153 | 1.4 (± 3.87) | -0.4 (± 2.85) | | |
| NNRTI, Bilirubin, Week 8, n=122, 152 | 1.4 (± 3.84) | -0.4 (± 2.43) | | |
| NNRTI, Bilirubin, Week 12, n=146, 152 | 2.0 (± 4.69) | -0.2 (± 3.01) | | |
| NNRTI, Bilirubin, Week 16, n=143, 149 | 3.3 (± 14.12) | -0.5 (± 2.66) | | |
| NNRTI, Bilirubin, Week 20, n=138, 152 | 2.1 (± 4.90) | -0.1 (± 2.81) | | |
| NNRTI, Bilirubin, Week 24, n=143, 151 | 1.8 (± 3.91) | -0.3 (± 2.84) | | |
| NNRTI, Bilirubin, Week 28, n=136, 150 | 2.4 (± 4.11) | -0.4 (± 3.04) | | |
| NNRTI, Bilirubin, Week 32, n=137, 148 | 2.2 (± 4.76) | -0.3 (± 2.57) | | |
| NNRTI, Bilirubin, Week 36, n=135, 147 | 1.8 (± 4.14) | -0.2 (± 2.61) | | |
| NNRTI, Bilirubin, Week 40, n=138, 147 | 2.2 (± 4.43) | -0.2 (± 2.61) | | |
| NNRTI, Bilirubin, Week 44, n=137, 148 | 2.0 (± 4.15) | -0.1 (± 2.72) | | |
| NNRTI, Bilirubin, Week 48, n=131, 147 | 2.2 (± 4.59) | 0.1 (± 2.98) | | |
| PI, Direct bilirubin, Week 4, n=51, 53 | -1.2 (± 2.34) | 0.3 (± 1.40) | | |
| PI, Direct bilirubin, Week 8, n=34, 53 | -0.9 (± 2.16) | -0.1 (± 1.44) | | |
| PI, Direct bilirubin, Week 12, n=50, 52 | -1.6 (± 2.16) | 0.3 (± 1.39) | | |
| PI, Direct bilirubin, Week 16, n=48, 53 | -1.7 (± 2.12) | 0.0 (± 1.30) | | |
| PI, Direct bilirubin, Week 20, n=46, 53 | -1.5 (± 2.27) | 0.0 (± 1.86) | | |
| PI, Direct bilirubin, Week 24, n=47, 53 | -1.4 (± 2.27) | 0.2 (± 1.72) | | |
| PI, Direct bilirubin, Week 28, n=42, 53 | -1.6 (± 2.43) | -0.3 (± 1.52) | | |
| PI, Direct bilirubin, Week 32, n=45, 51 | -1.4 (± 2.48) | 0.2 (± 1.74) | | |
| PI, Direct bilirubin, Week 36, n=44, 50 | -1.8 (± 2.29) | 0.2 (± 1.49) | | |
| PI, Direct bilirubin, Week 40, n=42, 51 | -1.8 (± 2.29) | 0.2 (± 1.43) | | |
| PI, Direct bilirubin, Week 44, n=47, 51 | -1.5 (± 2.22) | 0.3 (± 1.52) | | |
| PI, Direct bilirubin, Week 48, n=43, 50 | -1.5 (± 2.35) | 0.2 (± 1.36) | | |
| INI, Direct bilirubin, Week 4, n=99, 97 | 0.0 (± 1.11) | 0.0 (± 1.19) | | |
| INI, Direct bilirubin, Week 8, n=73, 98 | 0.0 (± 1.13) | 0.7 (± 6.76) | | |

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|--|------------------|-----------------|--|--|
| INI, Direct bilirubin, Week 12, n=99, 95 | 0.0 (± 1.14) | 0.0 (± 1.29) | | |
| INI, Direct bilirubin, Week 16, n=93, 96 | 0.0 (± 1.14) | -0.3 (± 1.06) | | |
| INI, Direct bilirubin, Week 20, n=93, 97 | -0.2 (± 0.96) | -0.2 (± 1.23) | | |
| INI, Direct bilirubin, Week 24, n=94, 94 | -0.1 (± 1.07) | -0.3 (± 1.16) | | |
| INI, Direct bilirubin, Week 28, n=89, 93 | -0.1 (± 0.97) | -0.2 (± 1.30) | | |
| INI, Direct bilirubin, Week 32, n=93, 95 | -0.2 (± 1.24) | -0.4 (± 1.15) | | |
| INI, Direct bilirubin, Week 36, n=94, 95 | -0.2 (± 1.33) | -0.3 (± 1.18) | | |
| INI, Direct bilirubin, Week 40, n=90, 95 | -0.1 (± 1.10) | -0.4 (± 1.24) | | |
| INI, Direct bilirubin, Week 44, n=91, 94 | 0.0 (± 1.14) | -0.3 (± 1.11) | | |
| INI, Direct bilirubin, Week 48, n=91, 95 | 0.0 (± 1.01) | -0.1 (± 1.28) | | |
| NNRTI, Direct bilirubin, Week 4, n=151, 153 | 0.1 (± 1.14) | 0.1 (± 1.12) | | |
| NNRTI, Direct bilirubin, Week 8, n=122, 152 | 0.1 (± 1.24) | 0.0 (± 1.03) | | |
| NNRTI, Direct bilirubin, Week 12, n=146, 152 | 0.2 (± 1.38) | 0.0 (± 1.08) | | |
| NNRTI, Direct bilirubin, Week 16, n=143, 149 | 0.7 (± 6.82) | -0.1 (± 1.09) | | |
| NNRTI, Direct bilirubin, Week 20, n=138, 152 | 0.1 (± 1.32) | -0.2 (± 1.08) | | |
| NNRTI, Direct bilirubin, Week 24, n=143, 151 | 0.1 (± 1.34) | -0.1 (± 1.06) | | |
| NNRTI, Direct bilirubin, Week 28, n=136, 150 | 0.1 (± 1.29) | -0.2 (± 1.19) | | |
| NNRTI, Direct bilirubin, Week 32, n=137, 148 | 0.0 (± 1.31) | -0.2 (± 1.06) | | |
| NNRTI, Direct bilirubin, Week 36, n=135, 147 | 0.0 (± 1.47) | -0.2 (± 1.09) | | |
| NNRTI, Direct bilirubin, Week 40, n=138, 147 | 0.0 (± 1.55) | -0.2 (± 1.01) | | |
| NNRTI, Direct bilirubin, Week 44, n=137, 148 | 0.1 (± 1.28) | -0.1 (± 1.08) | | |
| NNRTI, Direct bilirubin, Week 48, n=131, 147 | 0.1 (± 1.27) | 0.0 (± 1.16) | | |
| PI, Creatinine, Week 4, n=51, 53 | 1.46 (± 7.726) | 2.16 (± 6.737) | | |
| PI, Creatinine, Week 8, n=34, 53 | 0.87 (± 7.777) | 1.17 (± 5.605) | | |
| PI, Creatinine, Week 12, n=50, 52 | -1.66 (± 8.971) | 3.01 (± 5.406) | | |
| PI, Creatinine, Week 16, n=48, 53 | -0.90 (± 8.658) | 2.88 (± 5.918) | | |
| PI, Creatinine, Week 20, n=46, 53 | 1.63 (± 8.709) | 5.00 (± 9.336) | | |
| PI, Creatinine, Week 24, n=47, 53 | 0.48 (± 7.143) | 2.47 (± 6.821) | | |
| PI, Creatinine, Week 28, n=42, 53 | 3.06 (± 9.741) | 3.05 (± 6.908) | | |
| PI, Creatinine, Week 32, n=45, 51 | 2.29 (± 10.124) | 3.79 (± 6.540) | | |
| PI, Creatinine, Week 36, n=44, 50 | 2.20 (± 7.347) | 2.36 (± 6.291) | | |
| PI, Creatinine, Week 40, n=42, 51 | 1.10 (± 9.155) | 3.46 (± 6.166) | | |
| PI, Creatinine, Week 44, n=47, 51 | 3.01 (± 8.981) | 2.73 (± 6.169) | | |
| PI, Creatinine, Week 48, n=43, 50 | 4.41 (± 10.009) | 1.86 (± 5.575) | | |
| INI, Creatinine, Week 4, n=99, 95 | -1.61 (± 8.848) | 1.64 (± 10.592) | | |
| INI, Creatinine, Week 8, n=73, 98 | -3.93 (± 10.030) | 1.56 (± 9.444) | | |
| INI, Creatinine, Week 12, n=99, 95 | -2.47 (± 10.973) | 3.03 (± 10.203) | | |
| INI, Creatinine, Week 16, n=93, 96 | -3.93 (± 9.000) | 0.36 (± 8.651) | | |

| | | | | |
|--|------------------|-----------------|--|--|
| INI, Creatinine, Week 20, n=93, 97 | -3.73 (± 9.101) | 0.86 (± 9.608) | | |
| INI, Creatinine, Week 24, n=94, 94 | -4.25 (± 8.281) | 0.87 (± 10.493) | | |
| INI, Creatinine, Week 28, n=89, 93 | -3.54 (± 10.713) | 0.92 (± 10.086) | | |
| INI, Creatinine, Week 32, n=93, 95 | -3.48 (± 10.591) | 0.86 (± 9.754) | | |
| INI, Creatinine, Week 36, n=94, 95 | -4.31 (± 10.360) | 1.34 (± 9.369) | | |
| INI, Creatinine, Week 40, n=90, 95 | -3.08 (± 9.913) | 1.66 (± 10.272) | | |
| INI, Creatinine, Week 44, n=91, 94 | -3.33 (± 9.165) | 0.98 (± 10.443) | | |
| INI, Creatinine, Week 48, n=91, 95 | -2.99 (± 9.442) | 0.47 (± 9.602) | | |
| NNRTI, Creatinine, Week 4, n=151, 153 | 2.86 (± 7.456) | 1.77 (± 6.484) | | |
| NNRTI, Creatinine, Week 8, n=122, 152 | 0.86 (± 8.263) | 1.05 (± 6.790) | | |
| NNRTI, Creatinine, Week 12, n=146, 152 | 1.47 (± 7.928) | 0.44 (± 6.096) | | |
| NNRTI, Creatinine, Week 16, n=143, 149 | 1.67 (± 8.934) | 1.98 (± 8.475) | | |
| NNRTI, Creatinine, Week 20, n=138, 152 | 3.04 (± 8.836) | 1.27 (± 7.023) | | |
| NNRTI, Creatinine, Week 24, n=143, 151 | 4.42 (± 14.819) | 1.28 (± 6.553) | | |
| NNRTI, Creatinine, Week 28, n=136, 150 | 3.61 (± 10.627) | 1.50 (± 7.483) | | |
| NNRTI, Creatinine, Week 32, n=137, 148 | 2.26 (± 9.033) | 2.01 (± 7.811) | | |
| NNRTI, Creatinine, Week 36, n=135, 147 | 2.98 (± 10.596) | 1.54 (± 7.354) | | |
| NNRTI, Creatinine, Week 40, n=138, 147 | 3.39 (± 9.496) | 0.99 (± 7.471) | | |
| NNRTI, Creatinine, Week 44, n=137, 148 | 3.24 (± 8.892) | 1.21 (± 6.686) | | |
| NNRTI, Creatinine, Week 48, n=131, 147 | 3.84 (± 11.860) | 0.69 (± 7.241) | | |

Notes:

[129] - Safety Population

[130] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Creatinine clearance

| | |
|-----------------|---|
| End point title | Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Creatinine clearance |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: creatinine clearance to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). GFR will be estimated by the central laboratory using the CKD-EPI. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[131] | 308 ^[132] | | |
| Units: Milliliters per minute per 1.73meter ² | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Week 4, n=51, 53 | -2.2 (± 9.77) | -2.8 (± 8.02) | | |
| PI, Week 8, n=34, 53 | -1.1 (± 10.19) | -1.3 (± 6.58) | | |
| PI, Week 12, n=50, 52 | 2.2 (± 11.04) | -3.7 (± 6.99) | | |
| PI, Week 16, n=48, 53 | 0.9 (± 11.02) | -3.1 (± 7.63) | | |
| PI, Week 20, n=46, 53 | -2.2 (± 10.80) | -5.0 (± 9.26) | | |
| PI, Week 24, n=47, 53 | -1.0 (± 8.60) | -3.8 (± 8.51) | | |
| PI, Week 28, n=42, 53 | -4.2 (± 11.82) | -4.0 (± 8.46) | | |
| PI, Week 32, n=45, 51 | -3.2 (± 12.30) | -5.2 (± 7.56) | | |
| PI, Week 36, n=44, 50 | -3.8 (± 8.68) | -3.6 (± 8.08) | | |
| PI, Week 40, n=42, 51 | -2.4 (± 10.71) | -4.9 (± 7.25) | | |
| PI, Week 44, n=47, 51 | -4.5 (± 10.63) | -4.2 (± 7.58) | | |
| PI, Week 48, n=43, 50 | -5.6 (± 12.22) | -3.1 (± 6.54) | | |
| INI, Week 4, n=99, 95 | 1.0 (± 9.51) | -2.0 (± 11.28) | | |
| INI, Week 8, n=72, 98 | 3.9 (± 9.84) | -1.9 (± 9.28) | | |
| INI, Week 12, n=99, 93 | 2.1 (± 11.32) | -3.1 (± 9.60) | | |
| INI, Week 16, n=93, 96 | 3.6 (± 9.71) | -0.7 (± 8.59) | | |
| INI, Week 20, n=93, 97 | 3.5 (± 9.77) | -1.7 (± 9.58) | | |
| INI, Week 24, n=94, 94 | 3.9 (± 9.26) | -1.8 (± 10.38) | | |
| INI, Week 28, n=89, 93 | 3.1 (± 11.02) | -1.6 (± 9.55) | | |
| INI, Week 32, n=92, 95 | 3.0 (± 10.40) | -2.0 (± 9.69) | | |
| INI, Week 36, n=94, 95 | 3.7 (± 11.19) | -2.3 (± 9.30) | | |
| INI, Week 40, n=89, 95 | 2.7 (± 10.45) | -2.6 (± 10.14) | | |
| INI, Week 44, n=91, 94 | 2.6 (± 9.88) | -1.6 (± 10.90) | | |
| INI, Week 48, n=90, 94 | 3.0 (± 9.74) | -1.6 (± 9.73) | | |
| NNRTI, Week 4, n=151, 153 | -3.4 (± 9.06) | -2.3 (± 8.10) | | |
| NNRTI, Week 8, n=121, 152 | -1.1 (± 9.35) | -1.3 (± 7.72) | | |
| NNRTI, Week 12, n=146, 152 | -1.7 (± 8.90) | -0.5 (± 7.03) | | |
| NNRTI, Week 16, n=143, 148 | -1.8 (± 10.60) | -2.3 (± 9.06) | | |
| NNRTI, Week 20, n=138, 152 | -3.7 (± 9.64) | -1.9 (± 7.41) | | |
| NNRTI, Week 24, n=142, 151 | -4.3 (± 10.67) | -2.0 (± 7.67) | | |
| NNRTI, Week 28, n=136, 150 | -4.3 (± 10.68) | -2.4 (± 8.67) | | |
| NNRTI, Week 32, n=137, 148 | -3.3 (± 10.42) | -2.8 (± 8.80) | | |
| NNRTI, Week 36, n=135, 147 | -3.8 (± 10.97) | -2.5 (± 8.16) | | |
| NNRTI, Week 40, n=137, 147 | -4.4 (± 9.97) | -2.0 (± 8.90) | | |
| NNRTI, Week 44, n=136, 148 | -4.4 (± 9.75) | -2.0 (± 7.45) | | |
| NNRTI, Week 48, n=131, 147 | -5.2 (± 11.72) | -1.6 (± 8.25) | | |

Notes:

[131] - Safety Population

[132] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Lipase

| | |
|-----------------|---|
| End point title | Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48: Lipase |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: lipase to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[133] | 308 ^[134] | | |
| Units: Units per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Week 4, n=51, 53 | -2.2 (± 16.83) | 1.2 (± 19.34) | | |
| PI, Week 8, n=34, 53 | -2.6 (± 6.71) | 2.5 (± 25.36) | | |
| PI, Week 12, n=49, 52 | -1.4 (± 17.24) | -2.2 (± 15.95) | | |
| PI, Week 16, n=47, 53 | -0.5 (± 18.71) | 1.4 (± 17.40) | | |
| PI, Week 20, n=46, 53 | -2.5 (± 17.90) | -0.6 (± 17.49) | | |
| PI, Week 24, n=47, 53 | -2.0 (± 16.61) | -2.7 (± 16.30) | | |
| PI, Week 28, n=42, 53 | -0.7 (± 18.60) | 0.2 (± 16.18) | | |
| PI, Week 32, n=45, 51 | -2.2 (± 19.27) | 2.5 (± 18.35) | | |
| PI, Week 36, n=44, 50 | -0.8 (± 17.96) | -1.2 (± 18.18) | | |
| PI, Week 40, n=42, 51 | 2.2 (± 26.77) | -1.8 (± 19.40) | | |
| PI, Week 44, n=47, 51 | -1.2 (± 18.28) | 1.4 (± 17.94) | | |
| PI, Week 48, n=43, 50 | -1.5 (± 19.38) | -1.3 (± 15.73) | | |
| INI, Week 4, n=99, 97 | 8.1 (± 34.32) | 3.8 (± 30.44) | | |
| INI, Week 8, n=72, 98 | 0.7 (± 9.79) | -0.5 (± 14.46) | | |
| INI, Week 12, n=99, 93 | 4.3 (± 17.70) | 1.8 (± 21.29) | | |
| INI, Week 16, n=93, 97 | 4.4 (± 22.42) | 0.6 (± 16.13) | | |
| INI, Week 20, n=94, 97 | 2.5 (± 17.23) | 0.9 (± 17.07) | | |
| INI, Week 24, n=94, 95 | 2.2 (± 15.17) | 2.2 (± 18.91) | | |
| INI, Week 28, n=89, 94 | 5.6 (± 28.06) | 5.1 (± 24.20) | | |
| INI, Week 32, n=92, 95 | 3.2 (± 18.68) | 5.4 (± 22.79) | | |
| INI, Week 36, n=94, 95 | 5.2 (± 21.04) | 0.1 (± 13.82) | | |
| INI, Week 40, n=89, 95 | 3.5 (± 11.71) | 1.7 (± 16.60) | | |
| INI, Week 44, n=91, 94 | 4.3 (± 21.59) | 4.8 (± 23.54) | | |
| INI, Week 48, n=90, 94 | 5.0 (± 24.95) | 3.9 (± 23.48) | | |
| NNRTI, Week 4, n=151, 153 | 5.7 (± 50.44) | 0.1 (± 20.35) | | |
| NNRTI, Week 8, n=121, 152 | 2.6 (± 25.04) | 1.5 (± 16.94) | | |

| | | | | |
|----------------------------|---------------|----------------|--|--|
| NNRTI, Week 12, n=146, 152 | 3.0 (± 30.94) | -1.9 (± 17.59) | | |
| NNRTI, Week 16, n=145, 149 | 2.5 (± 27.82) | 6.1 (± 40.62) | | |
| NNRTI, Week 20, n=138, 152 | 0.9 (± 13.53) | 1.3 (± 37.14) | | |
| NNRTI, Week 24, n=142, 151 | 3.4 (± 24.81) | 5.4 (± 28.22) | | |
| NNRTI, Week 28, n=136, 150 | 0.8 (± 24.38) | 1.2 (± 15.79) | | |
| NNRTI, Week 32, n=137, 148 | 9.1 (± 78.96) | 1.9 (± 21.30) | | |
| NNRTI, Week 36, n=135, 147 | 6.9 (± 68.07) | 1.7 (± 19.14) | | |
| NNRTI, Week 40, n=138, 147 | 7.1 (± 43.53) | 0.5 (± 17.62) | | |
| NNRTI, Week 44, n=136, 148 | 1.6 (± 24.46) | 1.1 (± 20.52) | | |
| NNRTI, Week 48, n=131, 146 | 3.1 (± 32.54) | 0.9 (± 16.60) | | |

Notes:

[133] - Safety Population

[134] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48

| | |
|-----------------|---|
| End point title | Change from Baseline values for clinical chemistry parameters using baseline third agent treatment class overtime including Week 48 |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: CO₂, chloride, glucose, phosphate, potassium, sodium and urea to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles)

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

End point timeframe:

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

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[135] | 308 ^[136] | | |
| Units: Millimoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, CO ₂ , Week 4, n=51, 53 | 1.3 (± 2.63) | 0.7 (± 2.34) | | |
| PI, CO ₂ , Week 8, n=34, 53 | 0.4 (± 2.36) | 0.3 (± 2.65) | | |
| PI, CO ₂ , Week 12, n=50, 52 | 0.7 (± 2.84) | 0.2 (± 2.23) | | |
| PI, CO ₂ , Week 16, n=48, 53 | 0.8 (± 2.60) | 0.2 (± 2.32) | | |
| PI, CO ₂ , Week 20, n=46, 53 | 0.9 (± 2.53) | 0.0 (± 2.26) | | |
| PI, CO ₂ , Week 24, n=47, 53 | 0.4 (± 2.23) | 0.1 (± 1.94) | | |
| PI, CO ₂ , Week 28, n=42, 53 | 0.6 (± 2.54) | -0.2 (± 2.37) | | |
| PI, CO ₂ , Week 32, n=45, 51 | 0.5 (± 2.35) | -0.2 (± 2.36) | | |
| PI, CO ₂ , Week 36, n=44, 50 | 0.5 (± 2.38) | -0.4 (± 1.98) | | |
| PI, CO ₂ , Week 40, n=42, 51 | 0.5 (± 2.10) | 0.3 (± 2.26) | | |
| PI, CO ₂ , Week 44, n=47, 51 | 0.7 (± 2.29) | 0.3 (± 2.18) | | |
| PI, CO ₂ , Week 48, n=43, 50 | 0.9 (± 2.69) | -0.1 (± 1.87) | | |

| | | | | |
|--------------------------------------|---------------|---------------|--|--|
| INI, CO2, Week 4, n=99, 97 | 1.0 (± 2.37) | 0.8 (± 2.21) | | |
| INI, CO2, Week 8, n=73, 98 | 0.5 (± 2.29) | 0.6 (± 2.46) | | |
| INI, CO2, Week 12, n=99, 95 | 0.4 (± 2.27) | 0.3 (± 2.31) | | |
| INI, CO2, Week 16, n=93, 96 | 0.1 (± 2.56) | 0.6 (± 2.53) | | |
| INI, CO2, Week 20, n=93, 97 | 0.1 (± 2.07) | 0.7 (± 2.25) | | |
| INI, CO2, Week 24, n=94, 95 | 0.1 (± 2.32) | 0.2 (± 2.49) | | |
| INI, CO2, Week 28, n=89, 93 | -0.3 (± 2.30) | 0.2 (± 2.41) | | |
| INI, CO2, Week 32, n=93, 95 | 0.2 (± 2.33) | 0.1 (± 2.34) | | |
| INI, CO2, Week 36, n=94, 95 | 0.0 (± 2.36) | 0.5 (± 2.58) | | |
| INI, CO2, Week 40, n=90, 95 | 0.5 (± 2.43) | 0.3 (± 2.18) | | |
| INI, CO2, Week 44, n=91, 94 | 0.5 (± 2.36) | 0.7 (± 2.45) | | |
| INI, CO2, Week 48, n=91, 95 | 0.1 (± 2.12) | 0.3 (± 2.53) | | |
| NNRTI, CO2, Week 4, n=151, 153 | 0.9 (± 2.60) | 0.7 (± 2.18) | | |
| NNRTI, CO2, Week 8, n=122, 152 | 0.4 (± 2.32) | 0.8 (± 2.52) | | |
| NNRTI, CO2, Week 12, n=146, 152 | 0.5 (± 2.38) | 0.4 (± 2.51) | | |
| NNRTI, CO2, Week 16, n=143, 149 | 0.3 (± 2.25) | 0.5 (± 2.37) | | |
| NNRTI, CO2, Week 20, n=138, 152 | 0.1 (± 2.27) | 0.2 (± 2.35) | | |
| NNRTI, CO2, Week 24, n=143, 150 | 0.3 (± 2.63) | 0.3 (± 2.57) | | |
| NNRTI, CO2, Week 28, n=136, 150 | 0.1 (± 2.54) | 0.2 (± 2.40) | | |
| NNRTI, CO2, Week 32, n=137, 148 | -0.2 (± 2.39) | 0.4 (± 2.27) | | |
| NNRTI, CO2, Week 36, n=135, 147 | 0.1 (± 2.38) | 0.5 (± 2.37) | | |
| NNRTI, CO2, Week 40, n=138, 147 | 0.4 (± 2.64) | 0.5 (± 2.38) | | |
| NNRTI, CO2, Week 44, n=137, 148 | 0.4 (± 2.35) | 0.5 (± 2.01) | | |
| NNRTI, CO2, Week 48, n=131, 147 | -0.1 (± 2.47) | 0.3 (± 2.30) | | |
| PI, Chloride, Week 4, n=51, 53 | 0.5 (± 1.80) | 0.5 (± 2.34) | | |
| PI, Chloride, Week 8, n=34, 53 | 0.2 (± 2.59) | 0.7 (± 2.42) | | |
| PI, Chloride, Week 12, n=50, 52 | 0.5 (± 2.39) | 0.8 (± 2.20) | | |
| PI, Chloride, Week 16, n=48, 53 | 0.5 (± 2.46) | 1.0 (± 2.31) | | |
| PI, Chloride, Week 20, n=46, 53 | 0.8 (± 2.20) | 0.7 (± 2.30) | | |
| PI, Chloride, Week 24, n=47, 53 | 1.1 (± 2.07) | 1.3 (± 2.36) | | |
| PI, Chloride, Week 28, n=42, 53 | 1.5 (± 2.19) | 1.2 (± 3.06) | | |
| PI, Chloride, Week 32, n=45, 51 | 0.9 (± 2.43) | 0.9 (± 2.60) | | |
| PI, Chloride, Week 36, n=44, 50 | 1.0 (± 2.28) | 1.0 (± 3.00) | | |
| PI, Chloride, Week 40, n=42, 51 | 1.3 (± 2.35) | 1.1 (± 2.60) | | |
| PI, Chloride, Week 44, n=47, 51 | 1.1 (± 2.21) | 1.1 (± 2.57) | | |
| PI, Chloride, Week 48, n=43, 50 | 0.5 (± 2.10) | 0.9 (± 2.29) | | |
| INI, Chloride, Week 4, n=99, 97 | 0.3 (± 2.02) | 0.5 (± 1.96) | | |
| INI, Chloride, Week 8, n=73, 98 | 0.2 (± 2.02) | 0.1 (± 2.42) | | |
| INI, Chloride, Week 12, n=99, 95 | 0.4 (± 2.53) | 0.5 (± 2.27) | | |
| INI, Chloride, Week 16, n=93, 96 | 0.9 (± 2.45) | 0.7 (± 2.32) | | |
| INI, Chloride, Week 20, n=93, 97 | 1.0 (± 2.44) | 0.2 (± 2.31) | | |
| INI, Chloride, Week 24, n=94, 95 | 0.6 (± 2.46) | 0.5 (± 2.19) | | |
| INI, Chloride, Week 28, n=89, 93 | 0.8 (± 1.92) | 0.3 (± 2.37) | | |
| INI, Chloride, Week 32, n=93, 95 | 0.7 (± 2.39) | 0.7 (± 2.45) | | |
| INI, Chloride, Week 36, n=94, 95 | 0.8 (± 2.20) | 0.5 (± 2.32) | | |
| INI, Chloride, Week 40, n=90, 95 | 0.7 (± 2.24) | 0.4 (± 2.69) | | |
| INI, Chloride, Week 44, n=91, 94 | 0.7 (± 2.38) | 0.5 (± 2.41) | | |
| INI, Chloride, Week 48, n=91, 95 | 0.4 (± 2.37) | -0.3 (± 2.36) | | |
| NNRTI, Chloride, Week 4, n=151, 153 | 0.4 (± 2.15) | 0.6 (± 2.17) | | |
| NNRTI, Chloride, Week 8, n=122, 152 | 0.4 (± 2.05) | 0.7 (± 1.91) | | |
| NNRTI, Chloride, Week 12, n=146, 152 | 0.4 (± 2.12) | 0.5 (± 2.27) | | |
| NNRTI, Chloride, Week 16, n=143, 149 | 0.5 (± 2.37) | 0.8 (± 2.20) | | |

| | | | | |
|--------------------------------------|------------------|-------------------|--|--|
| NNRTI, Chloride, Week 20, n=138, 152 | 0.7 (± 2.27) | 1.1 (± 2.40) | | |
| NNRTI, Chloride, Week 24, n=143, 151 | 0.5 (± 2.60) | 1.1 (± 2.24) | | |
| NNRTI, Chloride, Week 28, n=136, 150 | 0.8 (± 2.38) | 1.3 (± 2.39) | | |
| NNRTI, Chloride, Week 32, n=137, 148 | 0.8 (± 2.44) | 1.1 (± 2.15) | | |
| NNRTI, Chloride, Week 36, n=135, 147 | 1.0 (± 2.15) | 1.1 (± 2.37) | | |
| NNRTI, Chloride, Week 40, n=138, 147 | 0.6 (± 2.20) | 1.0 (± 2.84) | | |
| NNRTI, Chloride, Week 44, n=137, 148 | 0.6 (± 2.07) | 1.0 (± 2.08) | | |
| NNRTI, Chloride, Week 48, n=131, 147 | 0.6 (± 2.45) | 0.5 (± 2.36) | | |
| PI, Glucose, Week 4, n=43, 43 | -0.08 (± 0.922) | 0.32 (± 0.401) | | |
| PI, Glucose, Week 8, n=25, 41 | 0.17 (± 0.513) | 0.22 (± 0.466) | | |
| PI, Glucose, Week 12, n=40, 42 | 0.03 (± 0.925) | 0.27 (± 0.494) | | |
| PI, Glucose, Week 16, n=39, 43 | 0.11 (± 1.163) | 0.28 (± 0.704) | | |
| PI, Glucose, Week 20, n=35, 41 | -0.07 (± 1.058) | 0.30 (± 0.799) | | |
| PI, Glucose, Week 24, n=38, 42 | 0.11 (± 0.705) | 0.32 (± 0.636) | | |
| PI, Glucose, Week 28, n=32, 43 | -0.03 (± 1.342) | 0.16 (± 0.441) | | |
| PI, Glucose, Week 32, n=36, 41 | 0.23 (± 1.148) | 0.29 (± 0.600) | | |
| PI, Glucose, Week 36, n=35, 41 | -0.01 (± 1.014) | 0.22 (± 0.483) | | |
| PI, Glucose, Week 40, n=34, 40 | 0.11 (± 1.035) | 0.18 (± 0.497) | | |
| PI, Glucose, Week 44, n=40, 40 | 0.01 (± 1.008) | 0.20 (± 0.278) | | |
| PI, Glucose, Week 48, n=39, 48 | -0.01 (± 0.977) | 0.11 (± 0.663) | | |
| INI, Glucose, Week 4, n=55, 52 | 0.30 (± 0.613) | 0.07 (± 0.774) | | |
| INI, Glucose, Week 8, n=36, 57 | 0.12 (± 0.595) | 0.21 (± 1.083) | | |
| INI, Glucose, Week 12, n=52, 55 | 0.36 (± 0.996) | 0.30 (± 1.357) | | |
| INI, Glucose, Week 16, n=53, 52 | 0.35 (± 1.437) | 0.13 (± 0.557) | | |
| INI, Glucose, Week 20, n=51, 57 | 0.25 (± 0.515) | -0.06 (± 0.676) | | |
| INI, Glucose, Week 24, n=59, 61 | 0.24 (± 0.596) | 0.04 (± 0.652) | | |
| INI, Glucose, Week 28, n=52, 62 | 0.17 (± 0.681) | 0.33 (± 0.763) | | |
| INI, Glucose, Week 32, n=53, 55 | 0.48 (± 1.071) | 0.32 (± 0.876) | | |
| INI, Glucose, Week 36, n=53, 57 | 0.34 (± 0.642) | 0.19 (± 1.063) | | |
| INI, Glucose, Week 40, n=59, 62 | 0.36 (± 0.922) | 0.14 (± 0.566) | | |
| INI, Glucose, Week 44, n=54, 57 | 0.33 (± 0.971) | 0.16 (± 0.626) | | |
| INI, Glucose, Week 48, n=81, 90 | 0.04 (± 0.577) | -0.03 (± 0.796) | | |
| NNRTI, Glucose, Week 4, n=116, 124 | 0.20 (± 0.666) | 0.24 (± 1.055) | | |
| NNRTI, Glucose, Week 8, n=90, 116 | 0.27 (± 0.987) | 0.23 (± 0.795) | | |
| NNRTI, Glucose, Week 12, n=112, 119 | 0.16 (± 0.746) | 0.11 (± 0.887) | | |
| NNRTI, Glucose, Week 16, n=115, 116 | 0.22 (± 0.767) | 0.33 (± 1.347) | | |
| NNRTI, Glucose, Week 20, n=106, 118 | 0.25 (± 0.636) | 0.28 (± 1.104) | | |
| NNRTI, Glucose, Week 24, n=115, 121 | 0.27 (± 0.763) | 0.16 (± 1.037) | | |
| NNRTI, Glucose, Week 28, n=104, 120 | 0.23 (± 0.596) | 0.30 (± 1.077) | | |
| NNRTI, Glucose, Week 32, n=103, 117 | 0.32 (± 0.811) | 0.24 (± 1.062) | | |
| NNRTI, Glucose, Week 36, n=102, 117 | 0.17 (± 0.789) | 0.31 (± 1.217) | | |
| NNRTI, Glucose, Week 40, n=100, 111 | 0.27 (± 0.692) | 0.33 (± 1.118) | | |
| NNRTI, Glucose, Week 44, n=99, 116 | 0.26 (± 0.793) | 0.35 (± 1.121) | | |
| NNRTI, Glucose, Week 48, n=118, 136 | 0.06 (± 0.659) | 0.02 (± 1.074) | | |
| PI, Phosphate, Week 4, n=51, 53 | 0.068 (± 0.1513) | 0.009 (± 0.1682) | | |
| PI, Phosphate, Week 8, n=34, 53 | 0.076 (± 0.2023) | -0.019 (± 0.1752) | | |

| | | | | |
|---------------------------------------|-------------------|-------------------|--|--|
| PI, Phosphate, Week 12, n=50, 52 | 0.025 (± 0.1794) | 0.007 (± 0.1524) | | |
| PI, Phosphate, Week 16, n=48, 53 | 0.056 (± 0.2028) | -0.008 (± 0.1610) | | |
| PI, Phosphate, Week 20, n=46, 53 | 0.069 (± 0.1864) | 0.017 (± 0.1924) | | |
| PI, Phosphate, Week 24, n=47, 53 | 0.037 (± 0.1971) | 0.018 (± 0.1735) | | |
| PI, Phosphate, Week 28, n=42, 53 | 0.035 (± 0.2140) | 0.017 (± 0.1971) | | |
| PI, Phosphate, Week 32, n=45, 51 | 0.053 (± 0.2191) | 0.032 (± 0.1545) | | |
| PI, Phosphate, Week 36, n=44, 50 | 0.032 (± 0.1818) | -0.001 (± 0.1828) | | |
| PI, Phosphate, Week 40, n=42, 51 | 0.027 (± 0.2392) | 0.001 (± 0.1657) | | |
| PI, Phosphate, Week 44, n=47, 51 | 0.033 (± 0.2107) | 0.011 (± 0.1736) | | |
| PI, Phosphate, Week 48, n=43, 50 | 0.048 (± 0.1994) | 0.017 (± 0.1387) | | |
| INI, Phosphate, Week 4, n=99, 97 | 0.036 (± 0.1518) | 0.017 (± 0.1588) | | |
| INI, Phosphate, Week 8, n=73, 98 | 0.056 (± 0.1532) | 0.010 (± 0.1676) | | |
| INI, Phosphate, Week 12, n=99, 95 | 0.024 (± 0.2108) | 0.017 (± 0.1808) | | |
| INI, Phosphate, Week 16, n=93, 96 | 0.031 (± 0.1895) | 0.001 (± 0.1708) | | |
| INI, Phosphate, Week 20, n=93, 97 | 0.012 (± 0.1764) | 0.025 (± 0.1823) | | |
| INI, Phosphate, Week 24, n=94, 95 | 0.031 (± 0.1501) | -0.011 (± 0.1785) | | |
| INI, Phosphate, Week 28, n=89, 93 | 0.032 (± 0.1628) | 0.006 (± 0.1806) | | |
| INI, Phosphate, Week 32, n=93, 95 | 0.012 (± 0.1751) | -0.017 (± 0.1827) | | |
| INI, Phosphate, Week 36, n=94, 95 | -0.002 (± 0.1496) | -0.001 (± 0.1979) | | |
| INI, Phosphate, Week 40, n=90, 95 | 0.018 (± 0.1766) | -0.002 (± 0.1721) | | |
| INI, Phosphate, Week 44, n=91, 94 | 0.005 (± 0.1695) | 0.005 (± 0.1977) | | |
| INI, Phosphate, Week 48, n=91, 95 | 0.028 (± 0.1684) | 0.002 (± 0.2072) | | |
| NNRTI, Phosphate, Week 4, n=151, 153 | 0.085 (± 0.1785) | 0.016 (± 0.1580) | | |
| NNRTI, Phosphate, Week 8, n=122, 152 | 0.061 (± 0.2002) | -0.012 (± 0.1515) | | |
| NNRTI, Phosphate, Week 12, n=146, 152 | 0.057 (± 0.1946) | 0.012 (± 0.1780) | | |
| NNRTI, Phosphate, Week 16, n=143, 149 | 0.043 (± 0.2088) | 0.008 (± 0.1613) | | |
| NNRTI, Phosphate, Week 20, n=138, 152 | 0.039 (± 0.1935) | -0.002 (± 0.1823) | | |
| NNRTI, Phosphate, Week 24, n=143, 151 | 0.050 (± 0.2220) | 0.012 (± 0.1923) | | |
| NNRTI, Phosphate, Week 28, n=136, 150 | 0.040 (± 0.1850) | -0.003 (± 0.1789) | | |
| NNRTI, Phosphate, Week 32, n=137, 148 | 0.018 (± 0.2056) | 0.011 (± 0.2020) | | |
| NNRTI, Phosphate, Week 36, n=135, 147 | 0.014 (± 0.2069) | -0.002 (± 0.1794) | | |

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|---------------------------------------|-----------------------|------------------------|--|--|
| NNRTI, Phosphate, Week 40, n=138, 147 | 0.026 (\pm 0.2095) | -0.006 (\pm 0.1783) | | |
| NNRTI, Phosphate, Week 44, n=137, 148 | 0.041 (\pm 0.2112) | 0.000 (\pm 0.1735) | | |
| NNRTI, Phosphate, Week 48, n=131, 147 | 0.034 (\pm 0.2220) | -0.001 (\pm 0.1619) | | |
| PI, Potassium, Week 4, n=51, 53 | 0.12 (\pm 0.369) | 0.20 (\pm 0.447) | | |
| PI, Potassium, Week 8, n=34, 53 | 0.05 (\pm 0.245) | 0.08 (\pm 0.307) | | |
| PI, Potassium, Week 12, n=50, 52 | 0.12 (\pm 0.353) | 0.19 (\pm 0.388) | | |
| PI, Potassium, Week 16, n=48, 53 | 0.02 (\pm 0.343) | 0.19 (\pm 0.398) | | |
| PI, Potassium, Week 20, n=46, 53 | 0.05 (\pm 0.338) | 0.18 (\pm 0.420) | | |
| PI, Potassium, Week 24, n=47, 53 | 0.01 (\pm 0.354) | 0.19 (\pm 0.384) | | |
| PI, Potassium, Week 28, n=42, 53 | 0.09 (\pm 0.338) | 0.15 (\pm 0.342) | | |
| PI, Potassium, Week 32, n=45, 51 | 0.02 (\pm 0.356) | 0.19 (\pm 0.408) | | |
| PI, Potassium, Week 36, n=44, 50 | 0.12 (\pm 0.363) | 0.14 (\pm 0.371) | | |
| PI, Potassium, Week 40, n=42, 51 | 0.09 (\pm 0.348) | 0.15 (\pm 0.394) | | |
| PI, Potassium, Week 44, n=47, 51 | 0.10 (\pm 0.409) | 0.21 (\pm 0.433) | | |
| PI, Potassium, Week 48, n=43, 50 | 0.02 (\pm 0.359) | 0.01 (\pm 0.409) | | |
| INI, Potassium, Week 4, n=99, 97 | 0.03 (\pm 0.308) | 0.08 (\pm 0.335) | | |
| INI, Potassium, Week 8, n=73, 98 | -0.02 (\pm 0.282) | 0.06 (\pm 0.483) | | |
| INI, Potassium, Week 12, n=99, 95 | 0.02 (\pm 0.316) | 0.01 (\pm 0.329) | | |
| INI, Potassium, Week 16, n=93, 96 | -0.01 (\pm 0.286) | 0.01 (\pm 0.319) | | |
| INI, Potassium, Week 20, n=93, 97 | 0.03 (\pm 0.333) | 0.00 (\pm 0.313) | | |
| INI, Potassium, Week 24, n=94, 95 | 0.02 (\pm 0.304) | 0.04 (\pm 0.315) | | |
| INI, Potassium, Week 28, n=89, 93 | 0.02 (\pm 0.422) | 0.03 (\pm 0.372) | | |
| INI, Potassium, Week 32, n=93, 95 | 0.02 (\pm 0.322) | 0.01 (\pm 0.289) | | |
| INI, Potassium, Week 36, n=94, 95 | 0.01 (\pm 0.345) | 0.05 (\pm 0.349) | | |
| INI, Potassium, Week 40, n=90, 95 | 0.01 (\pm 0.288) | 0.01 (\pm 0.329) | | |
| INI, Potassium, Week 44, n=91, 94 | 0.01 (\pm 0.265) | 0.00 (\pm 0.327) | | |
| INI, Potassium, Week 48, n=91, 95 | -0.03 (\pm 0.249) | -0.01 (\pm 0.292) | | |
| NNRTI, Potassium, Week 4, n=151, 153 | 0.05 (\pm 0.354) | 0.10 (\pm 0.368) | | |
| NNRTI, Potassium, Week 8, n=122, 152 | 0.02 (\pm 0.342) | 0.05 (\pm 0.355) | | |
| NNRTI, Potassium, Week 12, n=146, 152 | 0.02 (\pm 0.351) | 0.08 (\pm 0.353) | | |
| NNRTI, Potassium, Week 16, n=143, 149 | 0.03 (\pm 0.373) | 0.05 (\pm 0.320) | | |
| NNRTI, Potassium, Week 20, n=138, 152 | 0.04 (\pm 0.358) | 0.03 (\pm 0.355) | | |
| NNRTI, Potassium, Week 24, n=143, 150 | 0.04 (\pm 0.329) | 0.04 (\pm 0.324) | | |
| NNRTI, Potassium, Week 28, n=136, 150 | 0.03 (\pm 0.364) | 0.08 (\pm 0.412) | | |
| NNRTI, Potassium, Week 32, n=137, 148 | 0.01 (\pm 0.442) | 0.02 (\pm 0.348) | | |
| NNRTI, Potassium, Week 36, n=135, 147 | 0.02 (\pm 0.359) | 0.05 (\pm 0.360) | | |
| NNRTI, Potassium, Week 40, n=138, 147 | 0.05 (\pm 0.375) | 0.08 (\pm 0.342) | | |
| NNRTI, Potassium, Week 44, n=137, 148 | 0.08 (\pm 0.364) | 0.07 (\pm 0.366) | | |
| NNRTI, Potassium, Week 48, n=131, 147 | -0.02 (\pm 0.311) | 0.00 (\pm 0.329) | | |
| PI, Sodium, Week 4, n=51, 53 | 0.4 (\pm 1.93) | 0.3 (\pm 2.11) | | |
| PI, Sodium, Week 8, n=34, 53 | 0.9 (\pm 2.21) | 0.3 (\pm 2.25) | | |
| PI, Sodium, Week 12, n=50, 52 | 0.5 (\pm 2.09) | 0.7 (\pm 1.97) | | |

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| PI, Sodium, Week 16, n=48, 53 | 0.5 (± 2.30) | 0.3 (± 2.24) | | |
| PI, Sodium, Week 20, n=46, 53 | 0.6 (± 2.15) | 0.4 (± 2.12) | | |
| PI, Sodium, Week 24, n=47, 53 | 0.5 (± 2.33) | 0.4 (± 2.30) | | |
| PI, Sodium, Week 28, n=42, 53 | 1.3 (± 2.06) | 0.8 (± 2.75) | | |
| PI, Sodium, Week 32, n=45, 51 | 0.5 (± 2.47) | 0.5 (± 2.26) | | |
| PI, Sodium, Week 36, n=44, 50 | 0.8 (± 2.21) | 0.6 (± 2.63) | | |
| PI, Sodium, Week 40, n=42, 51 | 0.8 (± 2.20) | 0.7 (± 2.03) | | |
| PI, Sodium, Week 44, n=47, 51 | 0.8 (± 2.10) | 0.7 (± 2.49) | | |
| PI, Sodium, Week 48, n=43, 50 | 0.9 (± 1.98) | 0.8 (± 1.95) | | |
| INI, Sodium, Week 4, n=99, 97 | 0.3 (± 1.62) | 0.0 (± 1.97) | | |
| INI, Sodium, Week 8, n=73, 98 | 0.1 (± 1.98) | -0.3 (± 1.87) | | |
| INI, Sodium, Week 12, n=99, 95 | 0.3 (± 2.11) | 0.0 (± 1.69) | | |
| INI, Sodium, Week 16, n=93, 96 | 0.3 (± 1.95) | 0.4 (± 1.97) | | |
| INI, Sodium, Week 20, n=93, 97 | 0.5 (± 1.94) | 0.1 (± 1.86) | | |
| INI, Sodium, Week 24, n=94, 95 | 0.5 (± 1.79) | 0.0 (± 1.73) | | |
| INI, Sodium, Week 28, n=89, 93 | 0.5 (± 1.74) | -0.3 (± 1.93) | | |
| INI, Sodium, Week 32, n=93, 95 | 0.5 (± 1.87) | 0.2 (± 1.75) | | |
| INI, Sodium, Week 36, n=94, 95 | 0.4 (± 1.86) | 0.3 (± 1.88) | | |
| INI, Sodium, Week 40, n=90, 95 | 0.5 (± 1.91) | 0.2 (± 2.01) | | |
| INI, Sodium, Week 44, n=91, 94 | 0.5 (± 1.77) | 0.3 (± 1.93) | | |
| INI, Sodium, Week 48, n=91, 95 | 0.4 (± 2.00) | -0.1 (± 1.85) | | |
| NNRTI, Sodium, Week 4, n=151, 153 | 0.2 (± 1.95) | 0.1 (± 1.98) | | |
| NNRTI, Sodium, Week 8, n=122, 152 | 0.2 (± 1.91) | 0.0 (± 1.82) | | |
| NNRTI, Sodium, Week 12, n=146, 152 | 0.1 (± 2.04) | 0.1 (± 2.01) | | |
| NNRTI, Sodium, Week 16, n=143, 149 | -0.1 (± 2.28) | -0.2 (± 2.04) | | |
| NNRTI, Sodium, Week 20, n=138, 152 | -0.1 (± 2.14) | 0.3 (± 1.95) | | |
| NNRTI, Sodium, Week 24, n=143, 151 | 0.1 (± 2.14) | 0.3 (± 1.95) | | |
| NNRTI, Sodium, Week 28, n=136, 150 | 0.3 (± 2.29) | 0.2 (± 2.18) | | |
| NNRTI, Sodium, Week 32, n=137, 148 | 0.1 (± 2.01) | 0.5 (± 1.84) | | |
| NNRTI, Sodium, Week 36, n=135, 147 | 0.4 (± 2.05) | 0.5 (± 2.22) | | |
| NNRTI, Sodium, Week 40, n=138, 147 | 0.3 (± 2.04) | 0.5 (± 2.12) | | |
| NNRTI, Sodium, Week 44, n=137, 148 | 0.5 (± 2.17) | 0.5 (± 1.96) | | |
| NNRTI, Sodium, Week 48, n=131, 147 | 0.3 (± 2.39) | 0.4 (± 1.97) | | |
| PI, Urea, Week 4, n=51, 53 | 0.02 (± 1.449) | 0.01 (± 1.124) | | |
| PI, Urea, Week 8, n=34, 53 | 0.21 (± 1.142) | -0.02 (± 1.205) | | |
| PI, Urea, Week 12, n=50, 52 | 0.04 (± 1.446) | -0.01 (± 1.312) | | |
| PI, Urea, Week 16, n=48, 53 | 0.25 (± 1.309) | 0.20 (± 1.377) | | |
| PI, Urea, Week 20, n=46, 53 | 0.18 (± 1.425) | 0.17 (± 1.275) | | |
| PI, Urea, Week 24, n=47, 53 | 0.41 (± 1.248) | 0.10 (± 1.182) | | |
| PI, Urea, Week 28, n=42, 53 | 0.18 (± 1.352) | 0.00 (± 1.236) | | |
| PI, Urea, Week 32, n=45, 51 | 0.12 (± 1.567) | 0.16 (± 1.210) | | |
| PI, Urea, Week 36, n=44, 50 | 0.01 (± 1.449) | -0.13 (± 1.190) | | |
| PI, Urea, Week 40, n=42, 51 | 0.17 (± 1.291) | 0.33 (± 1.714) | | |
| PI, Urea, Week 44, n=47, 51 | 0.36 (± 1.258) | 0.13 (± 1.276) | | |
| PI, Urea, Week 48, n=43, 50 | 0.10 (± 1.303) | 0.13 (± 1.305) | | |
| INI, Urea, Week 4, n=99, 97 | -0.14 (± 1.477) | 0.19 (± 1.635) | | |
| INI, Urea, Week 8, n=73, 98 | -0.14 (± 1.799) | 0.01 (± 1.601) | | |
| INI, Urea, Week 12, n=99, 95 | 0.05 (± 1.554) | 0.21 (± 1.481) | | |

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| INI, Urea, Week 16, n=93, 96 | 0.01 (± 1.402) | 0.05 (± 1.375) | | |
| INI, Urea, Week 20, n=93, 97 | 0.01 (± 1.531) | 0.15 (± 1.495) | | |
| INI, Urea, Week 24, n=94, 95 | 0.04 (± 1.367) | 0.12 (± 1.441) | | |
| INI, Urea, Week 28, n=89, 93 | 0.01 (± 1.570) | -0.02 (± 1.579) | | |
| INI, Urea, Week 32, n=93, 95 | -0.09 (± 1.592) | 0.01 (± 1.522) | | |
| INI, Urea, Week 36, n=94, 95 | -0.10 (± 1.514) | -0.05 (± 1.478) | | |
| INI, Urea, Week 40, n=90, 95 | 0.01 (± 1.519) | 0.12 (± 1.469) | | |
| INI, Urea, Week 44, n=91, 94 | -0.16 (± 1.583) | -0.19 (± 1.721) | | |
| INI, Urea, Week 48, n=91, 95 | 0.11 (± 1.633) | -0.05 (± 1.304) | | |
| NNRTI, Urea, Week 4, n=151, 153 | 0.10 (± 1.265) | 0.04 (± 1.185) | | |
| NNRTI, Urea, Week 8, n=122, 152 | 0.16 (± 1.286) | 0.01 (± 1.252) | | |
| NNRTI, Urea, Week 12, n=146, 152 | 0.26 (± 1.290) | 0.06 (± 1.344) | | |
| NNRTI, Urea, Week 16, n=143, 149 | 0.07 (± 1.407) | 0.28 (± 1.609) | | |
| NNRTI, Urea, Week 20, n=138, 152 | 0.25 (± 1.296) | 0.07 (± 1.507) | | |
| NNRTI, Urea, Week 24, n=143, 151 | 0.33 (± 1.499) | 0.18 (± 1.276) | | |
| NNRTI, Urea, Week 28, n=136, 150 | 0.22 (± 1.549) | 0.02 (± 1.422) | | |
| NNRTI, Urea, Week 32, n=137, 148 | 0.41 (± 1.410) | 0.06 (± 1.416) | | |
| NNRTI, Urea, Week 36, n=135, 147 | 0.19 (± 1.339) | 0.04 (± 1.392) | | |
| NNRTI, Urea, Week 40, n=138, 147 | 0.32 (± 1.347) | -0.01 (± 1.339) | | |
| NNRTI, Urea, Week 44, n=137, 148 | 0.25 (± 1.346) | 0.10 (± 1.344) | | |
| NNRTI, Urea, Week 48, n=131, 147 | 0.37 (± 1.389) | -0.02 (± 1.325) | | |

Notes:

[135] - Safety Population

[136] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline values for fasting lipid panel using baseline third agent treatment class overtime including Week 48

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|-----------------|---|
| End point title | Change from Baseline values for fasting lipid panel using baseline third agent treatment class overtime including Week 48 |
|-----------------|---|

End point description:

Blood samples were collected for the analysis of fasting lipid panel: triglycerides, total cholesterol, HDL cholesterol and LDL cholesterol to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

Baseline (Day 1) and at Week 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[137] | 308 ^[138] | | |
| Units: Millimoles per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| PI, Triglycerides, Week 48, n=40, 45 | -0.733 (± 1.5612) | 0.060 (± 0.9960) | | |
| INI, Triglycerides, Week 48, n=72, 77 | -0.078 (± 0.4964) | -0.117 (± 0.8052) | | |
| NNRTI, Triglycerides, Week 48, n=119, 120 | -0.015 (± 0.6121) | -0.014 (± 0.6761) | | |
| PI, Cholesterol, Week 48, n=40, 45 | -0.06 (± 0.629) | 0.06 (± 0.744) | | |
| INI, Cholesterol, Week 48, n=72, 77 | 0.18 (± 0.614) | -0.12 (± 0.674) | | |
| NNRTI, Cholesterol, Week 48, n=119, 120 | 0.06 (± 0.743) | -0.02 (± 0.626) | | |
| PI, HDL cholesterol, Week 48, n=40, 45 | 0.130 (± 0.2272) | 0.001 (± 0.3429) | | |
| INI, HDL cholesterol, Week 48, n=72, 77 | 0.074 (± 0.2339) | -0.038 (± 0.2308) | | |
| NNRTI, HDL cholesterol, Week 48, n=119, 120 | -0.011 (± 0.2936) | 0.028 (± 0.2577) | | |
| PI, LDL cholesterol, Week 48, n=37, 43 | 0.075 (± 0.5774) | 0.043 (± 0.5545) | | |
| INI, LDL cholesterol, Week 48, n=71, 76 | 0.144 (± 0.4840) | -0.015 (± 0.5333) | | |
| NNRTI, LDL cholesterol, Week 48, n=116, 119 | 0.078 (± 0.6885) | -0.040 (± 0.5246) | | |

Notes:

[137] - Safety Population

[138] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with genotypic resistance using baseline third agent through Week 48

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| End point title | Number of participants with genotypic resistance using baseline third agent through Week 48 |
|-----------------|---|

End point description:

Plasma samples were collected from participants who met confirmed virologic withdrawal criteria to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Genotypic Resistance data for the following drugs: DTG, EVG, RAL, DLV, EFV, ETR, NVP, RPV, 3TC, ABC, FTC, TDF, ZDV, d4T, ddI, ATV, DRV, FPV, IDV, LPV, NFV, RTV, SQV and TPV in participants meeting CVF criteria has been presented. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

At the time of CVF

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|------------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3 ^[139] | 4 ^[140] | | |
| Units: Participants | | | | |
| PI, INI, DTG, resistant, n=1, 0 | 0 | 0 | | |
| PI, INI, DTG, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, INI, DTG, sensitive, n=1, 0 | 1 | 0 | | |
| PI, INI, EVG, resistant, n=1, 0 | 0 | 0 | | |
| PI, INI, EVG, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, INI, EVG, sensitive, n=1, 0 | 1 | 0 | | |
| PI, INI, RAL, resistant, n=1, 0 | 0 | 0 | | |
| PI, INI, RAL, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, INI, RAL, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, DLV, resistant, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, DLV, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, DLV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, EFV, resistant, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, EFV, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, EFV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, ETR, resistant, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, ETR, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, ETR, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, NVP, resistant, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, NVP, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, NVP, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, RPV, resistant, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, RPV, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, RPV, sensitive, n=1, 0 | 0 | 0 | | |
| PI, NRTI, 3TC, resistant, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, 3TC, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NRTI, 3TC, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, ABC, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ABC, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ABC, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, FTC, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, FTC, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NRTI, FTC, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, TDF, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, TDF, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NRTI, TDF, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, ZDV, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ZDV, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ZDV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, d4T, resistant, n=1, 0 | 0 | 0 | | |

| | | | | |
|--|---|---|--|--|
| PI, NRTI, d4T, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NRTI, d4T, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, ddI, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ddI, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ddI, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, ATV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, ATV, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, ATV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, ATV/r, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, ATV/r, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, ATV/r, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, DRV/r, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, DRV/r, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, DRV/r, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, FPV/r, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, FPV/r, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, FPV/r, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, IDV/r, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, IDV/r, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, IDV/r, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, LPV/r, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, LPV/r, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, LPV/r, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, NFV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, NFV, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, NFV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, RTV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, RTV, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, RTV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, SQV/r, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, SQV/r, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, SQV/r, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, TPV/r, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, TPV/r, resistance possible, n=1, 0 | 0 | 0 | | |
| PI, PI, TPV/r, sensitive, n=1, 0 | 1 | 0 | | |
| INI, INI, DTG, resistant, n=0, 3 | 0 | 0 | | |
| INI, INI, DTG, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, INI, DTG, sensitive, n=0, 3 | 0 | 3 | | |
| INI, INI, EVG, resistant, n=0, 3 | 0 | 0 | | |
| INI, INI, EVG, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, INI, EVG, sensitive, n=0, 3 | 0 | 3 | | |
| INI, INI, RAL, resistant, n=0, 3 | 0 | 0 | | |
| INI, INI, RAL, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, INI, RAL, sensitive, n=0, 3 | 0 | 3 | | |

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|--|---|---|--|--|
| INI, NNRTI, DLV, resistant, n=0, 3 | 0 | 0 | | |
| INI, INI, DLV, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, DLV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NNRTI, EFV, resistant, n=0, 3 | 0 | 0 | | |
| INI, INI, EFV, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, EFV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NNRTI, ETR, resistant,, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, ETR, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, ETR, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NNRTI, NVP, resistant, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, NVP, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, NVP, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NNRTI, RPV, resistant, n=0, 3 | 0 | 1 | | |
| INI, NNRTI, RPV, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, RPV, sensitive, n=0, 3 | 0 | 2 | | |
| INI, NRTI, 3TC, resistant, n=0, 3 | 0 | 1 | | |
| INI, NNRTI, 3TC, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NRTI, 3TC, sensitive, n=0, 3 | 0 | 2 | | |
| INI, NRTI, ABC, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ABC, resistance possible,, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ABC, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NRTI, FTC, resistant, n=0, 3 | 0 | 1 | | |
| INI, NRTI, FTC, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NRTI, FTC, sensitive, n=0, 3 | 0 | 2 | | |
| INI, NRTI, TDF, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, TDF, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NRTI, TDF, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NRTI, ZDV, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ZDV, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ZDV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NRTI, d4T, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, d4T, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, NRTI, d4T, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NRTI, ddI, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ddI, resistance possible, n=0, 3 | 0 | 1 | | |
| INI, NRTI, ddI, sensitive, n=0, 3 | 0 | 2 | | |
| INI, PI, ATV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, ATV, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, ATV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, ATV/r, n=0, 3 | 0 | 0 | | |
| INI, PI, ATV/r, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, ATV/r, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, DRV/r, resistant, n=0, 3 | 0 | 0 | | |

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|--|---|---|--|--|
| INI, PI, DRV/r, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, DRV/r, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, FPV/r, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, FPV/r, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, FPV/r, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, IDV/r, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, IDV/r, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, IDV/r, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, LPV/r, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, LPV/r, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, LPV/r, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, NFV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, NFV, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, NFV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, RTV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, RTV, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, RTV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, SQV/r, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, SQV/r, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, SQV/r, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, TPV/r, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, TPV/r, resistance possible, n=0, 3 | 0 | 0 | | |
| INI, PI, TPV/r, sensitive, n=0, 3 | 0 | 3 | | |
| NNRTI, INI, DTG, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, INI, DTG, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, INI, DTG, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, INI, EVG, resistant, n=2, 1 | 1 | 0 | | |
| NNRTI, INI, EVG, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, INI, EVG, sensitive, n=2, 1 | 1 | 1 | | |
| NNRTI, INI, RAL, resistant, n=2, 1 | 1 | 0 | | |
| NNRTI, INI, RAL, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, INI, RAL, sensitive, n=2, 1 | 1 | 1 | | |
| NNRTI, NNRTI, DLV, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, INI, DLV, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, NNRTI, DLV, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, NNRTI, EFV, resistant, n=2, 1 | 1 | 1 | | |
| NNRTI, INI, EFV, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, NNRTI, EFV, sensitive, n=2, 1 | 1 | 0 | | |
| NNRTI, NNRTI, ETR, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, NNRTI, ETR, resistance possible, n=2, 1 | 2 | 0 | | |
| NNRTI, NNRTI, ETR, sensitive, n=2, 1 | 0 | 1 | | |
| NNRTI, NNRTI, NVP, resistant, n=2, 1 | 1 | 1 | | |
| NNRTI, NNRTI, NVP, resistance possible, n=2, 1 | 0 | 0 | | |

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|--|---|---|--|--|
| NNRTI, NNRTI, NVP, sensitive, n=2, 1 | 1 | 0 | | |
| NNRTI, NNRTI, RPV, resistant, n=2, 1 | 2 | 0 | | |
| NNRTI, NNRTI, RPV, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, NNRTI, RPV, sensitive, n=2, 1 | 0 | 1 | | |
| NNRTI, NRTI, 3TC, resistant, n=2, 1 | 0 | 1 | | |
| NNRTI, NNRTI, 3TC, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, 3TC, sensitive, n=2, 1 | 2 | 0 | | |
| NNRTI, NRTI, ABC, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, ABC, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, ABC, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, NRTI, FTC, resistant, n=2, 1 | 0 | 1 | | |
| NNRTI, NRTI, FTC, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, FTC, sensitive, n=2, 1 | 2 | 0 | | |
| NNRTI, NRTI, TDF, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, TDF, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, TDF, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, NRTI, ZDV, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, ZDV, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, ZDV, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, NRTI, d4T, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, d4T, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, d4T, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, NRTI, ddI, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, NRTI, ddI, resistance possible, n=2, 1 | 0 | 1 | | |
| NNRTI, NRTI, ddI, sensitive, n=2, 1 | 2 | 0 | | |
| NNRTI, PI, ATV, resistant, n=2, 1 | 1 | 0 | | |
| NNRTI, PI, ATV, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, ATV, sensitive, n=2, 1 | 1 | 1 | | |
| NNRTI, PI, ATV/r, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, ATV/r, resistance possible, n=2, 1 | 1 | 0 | | |
| NNRTI, PI, ATV/r, sensitive, n=2, 1 | 1 | 1 | | |
| NNRTI, PI, DRV/r, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, DRV/r, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, DRV/r, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, PI, FPV/r, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, FPV/r, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, FPV/r, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, PI, IDV/r, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, IDV/r, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, IDV/r, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, PI, LPV/r, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, LPV/r, resistance possible, n=2, 1 | 0 | 0 | | |

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|---|---|---|--|--|
| NNRTI, PI, LPV/r, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, PI, NFV, resistant, n=2, 1 | 1 | 0 | | |
| NNRTI, PI, NFV, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, NFV, sensitive, n=2, 1 | 1 | 1 | | |
| NNRTI, PI, RTV, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, RTV, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, RTV, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, PI, SQV/r, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, SQV/r, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, SQV/r, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, PI, TPV/r, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, TPV/r, resistance possible, n=2, 1 | 0 | 0 | | |
| NNRTI, PI, TPV/r, sensitive, n=2, 1 | 2 | 1 | | |

Notes:

[139] - CVF Population

[140] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with phenotypic resistance using baseline third agent through Week 48

| | |
|-----------------|--|
| End point title | Number of participants with phenotypic resistance using baseline third agent through Week 48 |
|-----------------|--|

End point description:

Plasma samples were collected from participants who met confirmed virologic withdrawal criteria to assess the impact of Baseline third agent treatment class (PI, NNRTI and INI). Phenotypic Resistance data for the following drugs: CAB, DTG, EVG, RAL, DLV, EFV, ETR, NVP, RPV, 3TC, ABC, FTC, TDF, ZDV, d4T, ddI, ATV, DRV, FPV, IDV, LPV, NFV, RTV, SQV and TPV in participants meeting CVF criteria has been presented. Phenotypic resistance, partially sensitive, and Sensitive were defined based on FC value from Monogram as: resistance (FC > clinical higher cutoff/biologic cutoff), partially sensitive (FC ≤ clinical higher cutoff and > clinical lower cutoff), sensitive (FC ≤ clinical lower cutoff/biologic cutoff). 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:

At the time of CVF

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|---------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3 ^[141] | 4 ^[142] | | |
| Units: Participants | | | | |
| PI, INI, CAB, resistant , n=1, 0 | 0 | 0 | | |
| PI, INI, CAB, sensitive, n=1, 0 | 1 | 0 | | |
| PI, INI, DTG, resistant, n=1, 0 | 0 | 0 | | |
| PI, INI, DTG, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, INI, DTG, sensitive, n=1, 0 | 1 | 0 | | |

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|---|---|---|--|--|
| PI, INI, EVG, resistant, n=1, 0 | 0 | 0 | | |
| PI, INI, EVG, sensitive, n=1, 0 | 1 | 0 | | |
| PI, INI, RAL, resistant, n=1, 0 | 0 | 0 | | |
| PI, INI, RAL, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, DLV, resistant, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, DLV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, EFV, resistant, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, EFV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, ETR, resistant, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, ETR, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, ETR, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, NVP, resistant, n=1, 0 | 0 | 0 | | |
| PI, NNRTI, NVP, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, RPV, resistant, n=1, 0 | 1 | 0 | | |
| PI, NNRTI, RPV, sensitive, n=1, 0 | 0 | 0 | | |
| PI, NRTI, 3TC, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, 3TC, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, ABC, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ABC, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ABC, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, FTC, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, FTC, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, TDF, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, TDF, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, NRTI, TDF, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, ZDV, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ZDV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, d4T, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, d4T, sensitive, n=1, 0 | 1 | 0 | | |
| PI, NRTI, ddI, resistant, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ddI, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, NRTI, ddI, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, ATV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, ATV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, DRV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, DRV, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, PI, DRV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, FPV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, FPV, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, PI, FPV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, IDV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, IDV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, LPV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, LPV, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, PI, LPV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, NFV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, NFV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, RTV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, RTV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, SQV, resistant, n=1, 0 | 0 | 0 | | |

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|--|---|---|--|--|
| PI, PI, SQV, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, PI, SQV, sensitive, n=1, 0 | 1 | 0 | | |
| PI, PI, TPV, resistant, n=1, 0 | 0 | 0 | | |
| PI, PI, TPV, partially sensitive, n=1, 0 | 0 | 0 | | |
| PI, PI, TPV, sensitive, n=1, 0 | 1 | 0 | | |
| INI, INI, CAB, resistant, n=0, 3 | 0 | 0 | | |
| INI, INI, CAB, sensitive, n=0, 3 | 0 | 3 | | |
| INI, INI, DTG, resistant, n=0, 3 | 0 | 0 | | |
| INI, INI, DTG, partially sensitive, n=0, 3 | 0 | 0 | | |
| INI, INI, DTG, sensitive, n=0, 3 | 0 | 3 | | |
| INI, INI, EVG, resistant, n=0, 3 | 0 | 0 | | |
| INI, INI, EVG, sensitive, n=0, 3 | 0 | 3 | | |
| INI, INI, RAL, resistant, n=0, 3 | 0 | 0 | | |
| INI, INI, RAL, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NNRTI, DLV, resistant, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, DLV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NNRTI, EFV, resistant, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, EFV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NNRTI, ETR, resistant, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, ETR, partially sensitive, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, ETR, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NNRTI, NVP, resistant, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, NVP, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NNRTI, RPV, resistant, n=0, 3 | 0 | 0 | | |
| INI, NNRTI, RPV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NRTI, 3TC, resistant, n=0, 3 | 0 | 1 | | |
| INI, NRTI, 3TC, sensitive, n=0, 3 | 0 | 2 | | |
| INI, NRTI, ABC, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ABC, partially sensitive, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ABC, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NRTI, FTC, resistant, n=0, 3 | 0 | 1 | | |
| INI, NRTI, FTC, sensitive, n=0, 3 | 0 | 2 | | |
| INI, NRTI, TDF, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, TDF, partially sensitive, n=0, 3 | 0 | 0 | | |
| INI, NRTI, TDF, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NRTI, ZDV, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ZDV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NRTI, d4T, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, d4T, sensitive, n=0, 3 | 0 | 3 | | |
| INI, NRTI, ddI, resistant, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ddI, partially sensitive, n=0, 3 | 0 | 0 | | |
| INI, NRTI, ddI, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, ATV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, ATV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, DRV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, DRV, partially sensitive, n=0, 3 | 0 | 0 | | |
| INI, PI, DRV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, FPV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, FPV, partially sensitive, n=0, 3 | 0 | 0 | | |

| | | | | |
|--|---|---|--|--|
| INI, PI, FPV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, IDV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, IDV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, LPV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, LPV, partially sensitive, n=0, 3 | 0 | 0 | | |
| INI, PI, LPV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, NFV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, NFV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, RTV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, RTV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, SQV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, SQV, partially sensitive, n=0, 3 | 0 | 0 | | |
| INI, PI, SQV, sensitive, n=0, 3 | 0 | 3 | | |
| INI, PI, TPV, resistant, n=0, 3 | 0 | 0 | | |
| INI, PI, TPV, partially sensitive, n=0, 3 | 0 | 0 | | |
| INI, PI, TPV, sensitive, n=0, 3 | 0 | 3 | | |
| NNRTI, INI, CAB, resistant, n=2, 1 | 1 | 0 | | |
| NNRTI, INI, CAB, sensitive, n=2, 1 | 1 | 1 | | |
| NNRTI, INI, DTG, resistant, n=2, 1 | 0 | 0 | | |
| NNRTI, INI, DTG, partially sensitive, n=2, 1 | 0 | 0 | | |
| NNRTI, INI, DTG, sensitive, n=2, 1 | 2 | 1 | | |
| NNRTI, INI, EVG, resistant, n=2, 1 | 1 | 0 | | |
| NNRTI, INI, EVG, sensitive, n=2, 1 | 1 | 1 | | |
| NNRTI, INI, RAL, resistant, n=2, 1 | 1 | 0 | | |
| NNRTI, INI, RAL, sensitive, n=2, 1 | 1 | 1 | | |
| NNRTI, NNRTI, DLV, resistant, n=2, 0 | 2 | 0 | | |
| NNRTI, NNRTI, DLV, sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, NNRTI, EFV, resistant, n=2, 0 | 2 | 0 | | |
| NNRTI, NNRTI, EFV, sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, NNRTI, ETR, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, NNRTI, ETR, partially sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, NNRTI, ETR, sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, NNRTI, NVP, resistant, n=2, 0 | 2 | 0 | | |
| NNRTI, NNRTI, NVP, sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, NNRTI, RPV, resistant, n=2, 0 | 2 | 0 | | |
| NNRTI, NNRTI, RPV, sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, NRTI, 3TC, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, NRTI, 3TC, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, NRTI, ABC, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, NRTI, ABC, partially sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, NRTI, ABC, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, NRTI, FTC, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, NRTI, FTC, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, NRTI, TDF, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, NRTI, TDF, partially sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, NRTI, TDF, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, NRTI, ZDV, resistant, n=2, 0 | 1 | 0 | | |
| NNRTI, NRTI, ZDV, sensitive, n=2, 0 | 1 | 0 | | |
| NNRTI, NRTI, d4T, resistant, n=2, 0 | 0 | 0 | | |

| | | | | |
|---|---|---|--|--|
| NNRTI, NRTI, d4T, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, NRTI, ddI, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, NRTI, ddI, partially sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, NRTI, ddI, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, PI, ATV, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, ATV, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, PI, DRV, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, DRV, partially sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, DRV, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, PI, FPV, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, FPV, partially sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, FPV, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, PI, IDV, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, IDV, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, PI, LPV, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, LPV, partially sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, LPV, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, PI, NFV, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, NFV, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, PI, RTV, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, RTV, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, PI, SQV, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, SQV, partially sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, SQV, sensitive, n=2, 0 | 2 | 0 | | |
| NNRTI, PI, TPV, resistant, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, TPV, partially sensitive, n=2, 0 | 0 | 0 | | |
| NNRTI, PI, TPV, sensitive, n=2, 0 | 2 | 0 | | |

Notes:

[141] - CVF Population

[142] - CVF Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 5 in dimension scores using perception of injection questionnaire (PIN)-Last Observation Carried Forward (LOCF) in Q4W arm

| | |
|-----------------|--|
| End point title | Change from Week 5 in dimension scores using perception of injection questionnaire (PIN)-Last Observation Carried Forward (LOCF) in Q4W arm ^[143] |
|-----------------|--|

End point description:

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

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

End point timeframe:

Week 5 and at Weeks 41 and 48

Notes:

[143] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

| | | | | |
|--------------------------------------|------------------------|--|--|--|
| End point values | CAB LA+RPV LA (Q4W) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 296 ^[144] | | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Bother of ISRs, Week 41 | -0.21 (± 0.532) | | | |
| Bother of ISRs, Week 48 | -0.21 (± 0.524) | | | |
| Leg movement, Week 41 | -0.52 (± 0.903) | | | |
| Leg movement, Week 48 | -0.59 (± 0.950) | | | |
| Sleep, Week 41 | -0.56 (± 0.877) | | | |
| Sleep, Week 48 | -0.56 (± 0.937) | | | |
| Acceptance, Week 41 | -0.49 (± 1.094) | | | |
| Acceptance, Week 48 | -0.54 (± 1.080) | | | |

Notes:

[144] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with extremely or very acceptable pain and local reaction: acceptability score on PIN questionnaire in Q4W arm

| | |
|-----------------|--|
| End point title | Percentage of participants with extremely or very acceptable pain and local reaction: acceptability score on PIN questionnaire in Q4W arm ^[145] |
|-----------------|--|

End point description:

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

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

End point timeframe:

Weeks 5, 41 and 48

Notes:

[145] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

| End point values | CAB LA+RPV LA (Q4W) | | | |
|---|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 308 ^[146] | | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Local reaction, Week 5, total, n=296 | 141 | | | |
| Local reaction, Week 5, very acceptable, n=296 | 77 | | | |
| Local reaction, Week 5, moderate, n=296 | 54 | | | |
| Local reaction, Week 5, little, n=296 | 15 | | | |
| Local reaction, Week 5, not at all, n=296 | 9 | | | |
| Pain, Week 5, total, n=296 | 86 | | | |
| Pain, Week 5, very acceptable, n=296 | 103 | | | |
| Pain, Week 5, moderate, n=296 | 59 | | | |
| Pain, Week 5, little, n=296 | 29 | | | |
| Pain, Week 5, not at all, n=296 | 19 | | | |
| Local reaction, Week 41, total, n=300 | 188 | | | |
| Local reaction, Week 41, very acceptable, n=300 | 77 | | | |
| Local reaction, Week 41, moderate, n=300 | 24 | | | |
| Local reaction, Week 41, little, n=300 | 6 | | | |
| Local reaction, Week 41, not at all, n=300 | 5 | | | |
| Pain, Week 41, total, n=300 | 166 | | | |
| Pain, Week 41, very acceptable, n=300 | 85 | | | |
| Pain, Week 41, moderate, n=300 | 31 | | | |
| Pain, Week 41, little, n=300 | 12 | | | |
| Pain, Week 41, not at all, n=300 | 6 | | | |
| Local reaction, week 48, total, n=303 | 202 | | | |
| Local reaction, Week 48, very acceptable, n=303 | 69 | | | |
| Local reaction, Week 48, moderate, n=303 | 21 | | | |
| Local reaction, Week 48, little, n=303 | 8 | | | |
| Local reaction, Week 48, not at all, n=303 | 3 | | | |
| Pain, Week 48, total, n=303 | 168 | | | |
| Pain, Week 48, very acceptable, n=303 | 95 | | | |
| Pain, Week 48, moderate, n=303 | 26 | | | |
| Pain, Week 48, little, n=303 | 11 | | | |
| Pain, Week 48, not at all, n=303 | 3 | | | |

Notes:

[146] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The HATQoL questionnaire was used to assess health related QoL (HRQoL). It comprises of three dimensions: LISAT, medication worries (MEDWO) and disclosure worries (DISWO). Total imputed value score for LISAT is calculated on a 0-100 scale using formula: $LISAT\ 100 = [100 \text{ divided by } (20 \text{ minus } 4)] * (LISAT \text{ minus } 4)$. A response of 5 in LISAT score shows satisfaction all of time and 1 as none of time. The higher the score, the greater satisfaction to life and the less worry. Transformed dimension score for each domain was summarized and analyzed. LOCF was used as primary method of analysis. Measure type was considered as mean for adjusted mean and dispersion measure as 95% confidence interval (CI). Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at specified data points were analyzed (represented by n= X in

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

End point timeframe:

Baseline (Day 1) and at Weeks 24 and 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[147] | 308 ^[148] | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 24, n=292, 291 | 1.0 (-0.6 to 2.6) | 1.1 (-0.5 to 2.7) | | |
| Week 48, n=292, 297 | 1.1 (-0.6 to 2.8) | 0.1 (-1.6 to 1.7) | | |

Notes:

[147] - ITT-E Population

[148] - ITT-E Population

Statistical analyses

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 1 |
|----------------------------|------------------------|

Statistical analysis description:

Treatment comparison at Week 24 for the groups CAB LA+ RPV LA and current ART is presented.

| | |
|---|-----------------------------------|
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.944 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | -0.1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.4 |
| upper limit | 2.2 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 2 |
|-----------------------------------|------------------------|

Statistical analysis description:

Treatment comparison at Week 48 for the groups CAB LA+ RPV LA and current ART is presented.

| | |
|---|-----------------------------------|
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.385 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.3 |
| upper limit | 3.4 |

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

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

End point description:

The HATQoL questionnaire was used to assess health related QoL (HRQoL). It comprises of three dimensions: LISAT, medication worries(MEDWO)and disclosure worries (DISWO). Total imputed value score for MEDWO is calculated on a 0-100 scale using formula: $MEDWO\ 100 = [100 \text{ divided by } (20 \text{ minus } 5)] * (MEDWO \text{ minus } 5)$. A response of 1 in MEDWO score shows less medication worries all of time and 5 as none of time. Higher the score, the greater satisfaction to life and less worry. Transformed dimension score for each domain was summarized and analyzed. LOCF was primary method of analysis. Measure type was considered as mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at specified data points were analyzed (represented by n= X in category titles)

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

End point timeframe:

Baseline and at Weeks 24 and 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[149] | 308 ^[150] | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 24, n=292, 290 | 4.2 (2.7 to 5.8) | -0.7 (-2.2 to 0.9) | | |
| Week 48, n=292, 296 | 4.0 (2.3 to 5.7) | -2.4 (-4.1 to -0.8) | | |

Notes:

[149] - ITT-E Population

[150] - ITT-E Population

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|--|-----------------------------------|
| Statistical analysis description: | |
| Treatment comparison at Week 24 for the groups CAB LA+ RPV LA and current ART is presented | |
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.001 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 4.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.8 |
| upper limit | 7.1 |

| Statistical analysis title | Statistical Analysis 2 |
|--|-----------------------------------|
| Statistical analysis description: | |
| Treatment comparison at Week 48 for the groups CAB LA+ RPV LA and current ART is presented | |
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.001 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 6.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4 |
| upper limit | 8.8 |

Secondary: Change from Baseline in DISWO using HATQoL

| | |
|-----------------|--|
| End point title | Change from Baseline in DISWO using HATQoL |
|-----------------|--|

End point description:

The HATQoL questionnaire was used to assess the health related QoL (HRQoL). It comprises of three dimensions: LISAT, medication worries (MEDWO) and disclosure worries (DISWO). Total imputed value score for DISWO is calculated on a 0-100 scale using the formula: $DISWO\ 100 = [100 \text{ divided by } (20 \text{ minus } 5)] * (DISWO \text{ minus } 5)$. A response of 1 in DISWO score shows less medication worries all of time and 5 as none of the time. Higher the score, the greater satisfaction to life and less worry. Transformed dimension score for each domain was summarized and analyzed. LOCF was used as primary method of analysis. Measure type was considered as mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at specified data points were analyzed (represented by n= X in category titles)

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

End point timeframe:

Baseline and at Weeks 24 and 48

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[151] | 308 ^[152] | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 24, n=291, 290 | 8.3 (5.6 to 11.0) | 3.0 (0.3 to 5.8) | | |
| Week 48, n=291, 296 | 4.6 (1.7 to 7.6) | 2.6 (-0.3 to 5.6) | | |

Notes:

[151] - ITT-E Population

[152] - ITT-E Population

Statistical analyses

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 1 |
|----------------------------|------------------------|

Statistical analysis description:

Treatment comparison at Week 24 for the groups CAB LA+ RPV LA and current ART is presented

| | |
|---|-----------------------------------|
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.008 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 5.3 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.4 |
| upper limit | 9.1 |

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical Analysis 2 |
| Statistical analysis description: | |
| Treatment comparison at Week 48 for the groups CAB LA+ RPV LA and current ART is presented | |
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.347 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.2 |
| upper limit | 6.2 |

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

| | |
|---|---|
| End point title | Change from Baseline in health status using 12-item short form survey (SF-12) |
| End point description: | |
| <p>The SF-12 questionnaire consists of 7 questions which measures degree of general health status and mental health distress. Each question is scored 0-5, except for question 2 scored 0-3. HRQoL using SF-12 for total score, physical component summary (PCS) and mental component summary (MCS) were assessed for two treatment groups. Missing Total or component scores was imputed using LOCF. PCS/MCS are calculated using computer software purchased from QualityMetric (http://www.qualitymetric.com). The higher the score, the better will be the health status. Measure type was considered as mean for adjusted mean and dispersion measure as 95% CI. Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at specified data points were analyzed (represented by n= X in category titles).</p> | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline and at Weeks 24 and 48 | |

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|---|-------------------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[153] | 308 ^[154] | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Total score, Week 24, n=291, 289 | 0.0 (-0.3 to 0.4) | -0.2 (-0.5 to 0.1) | | |
| Total score, Week 48, n=293, 296 | -0.0 (-0.4 to 0.3) | 0.0 (-0.3 to 0.4) | | |
| MCS, Week 24, n=289, 286 | 0.288 (-0.579 to 1.155) | -0.388 (-1.259 to 0.484) | | |
| MCS, Week 48, n=291, 293 | 0.260 (-0.638 to 1.158) | -0.375 (-1.270 to 0.520) | | |
| PCS, Week 24, n=286, 288 | 0.650 (0.087 to 1.213) | -0.047 (-0.608 to 0.514) | | |
| PCS, Week 48, n=288, 295 | 0.758 (0.184 to 1.332) | 0.062 (-0.505 to 0.629) | | |

Notes:

[153] - ITT-E Population

[154] - ITT-E Population

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|--|-----------------------------------|
| Statistical analysis description: | |
| Treatment comparison of SF-12 total scores at Week 24 for the groups CAB LA+ RPV LA and current ART is presented | |
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.344 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 0.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.2 |
| upper limit | 0.7 |

| Statistical analysis title | Statistical Analysis 2 |
|--|-----------------------------------|
| Statistical analysis description: | |
| Treatment comparison of SF-12 total scores at Week 48 for the groups CAB LA+ RPV LA and current ART is presented | |
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |

| | |
|---|---------------------|
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.785 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | -0.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.6 |
| upper limit | 0.4 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Treatment comparison of SF-12 MCS at Week 24 for the groups CAB LA+ RPV LA and current ART is presented

| | |
|---|-----------------------------------|
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.282 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 0.676 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.557 |
| upper limit | 1.909 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Treatment comparison of SF-12 MCS at Week 48 for the groups CAB LA+ RPV LA and current ART is presented

| | |
|---|-----------------------------------|
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.327 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 0.635 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.637 |
| upper limit | 1.907 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 5 |
|-----------------------------------|------------------------|

Statistical analysis description:

Treatment comparison of SF-12 PCS at Week 24 for the groups CAB LA+ RPV LA and current ART is presented

| | |
|---|-----------------------------------|
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.086 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 0.697 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.1 |
| upper limit | 1.494 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical Analysis 6 |
|-----------------------------------|------------------------|

Statistical analysis description:

Treatment comparison of SF-12 PCS at Week 48 for the groups CAB LA+ RPV LA and current ART is presented

| | |
|---|-----------------------------------|
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.092 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 0.696 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.113 |
| upper limit | 1.505 |

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

| | |
|-----------------|--|
| End point title | Change from Baseline in total treatment satisfaction using HIV |
|-----------------|--|

End point description:

HIVTSQ total treatment satisfaction score is computed with 1-11 items. Items 1-11 are summed to produce score with possible range:-33 to 33. Item 12 in scale calculated as individual score. Higher the score, greater improvement in satisfaction with treatment; lower score, greater the deterioration in satisfaction with treatment. A score of 0 represents no change. A maximum of 5 items can be missing, Missing scores are imputed with mean of completed item scores. If 6 or more items are missing, overall treatment satisfaction score should not be computed and will remain missing. LOCF was primary method of analysis. Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Data is presented with respect to actual treatment received by participants. Only those participants with data available at specified data points were analyzed (represented by n=X in category titles)

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

End point timeframe:

Baseline and at Weeks 4b, 24 and 44

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[155] | 308 ^[156] | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4b, n=295, 0 | 3.99 (± 8.982) | 99999 (± 99999) | | |
| Week 24, n=300, 288 | 6.39 (± 10.328) | 1.08 (± 8.510) | | |
| Week 44, n=300, 294 | 6.02 (± 10.808) | 0.54 (± 9.877) | | |

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Change in treatment satisfaction over time using HIVTSQ change (HIVTSQc) at Week 48 in Q4W arm

| | |
|-----------------|---|
| End point title | Change in treatment satisfaction over time using HIVTSQ change (HIVTSQc) at Week 48 in Q4W arm ^[157] |
|-----------------|---|

End point description:

The HIVTSQ total treatment satisfaction score is computed with 1-11 items. These 1-11 items are summed to produce score with possible range:-33 to 33. Item 12 in scale calculated as individual score. Higher the score, greater improvement in satisfaction with treatment; lower score, greater the deterioration in satisfaction with treatment. A score of 0 represents no change. A maximum of 5 items can be missing, missing scores are imputed with mean of completed item scores. If 6 or more items are missing, overall treatment satisfaction score should not be computed and will remain missing. LOCF was primary method of analysis. Baseline value is defined as latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Data has been presented with respect to actual treatment received to the participants. Only those participants with data available at specified data points were analyzed

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

End point timeframe:

Week 48

Notes:

[157] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

| | | | | |
|--------------------------------------|------------------------|--|--|--|
| End point values | CAB LA+RPV LA (Q4W) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 275 ^[158] | | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (standard deviation) | 29.05 (± 6.978) | | | |

Notes:

[158] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

ACCEPT questionnaire is generic medication acceptance measure assessing how participants weigh advantages and disadvantages of long-term medication. It consists 25 items, capture six dimensions. 3 questions focus on general acceptance of study medication will be analyzed. Items on scale are rated 1-5 scores: 1:totally disagree, 2:somewhat disagree, 3:somewhat agree, 4:totally agree and 5:I don't know. Total score of dimension is calculated as mean of recoded items of dimension and linearly transformed to scale from 0-100. Total Score=(mean of recoded items in dimension minus 1)divided by 2*100. LOCF was primary method of analysis. Measure type is mean for adjusted mean and dispersion measure: 95% CI. Baseline value is latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as value at post-dose visit minus Baseline value. Only those participants with data available at specified data points were analyzed (represented by n=X in category titles)

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

End point timeframe:

Baseline and at Weeks 8, 24 and 48

| | | | | |
|---|------------------------|----------------------|--|--|
| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[159] | 308 ^[160] | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 8, n=302, 287 | 8.9 (6.3 to 11.6) | 1.0 (-1.7 to 3.8) | | |
| Week 24, n=303, 295 | 12.3 (9.9 to 14.8) | 5.5 (3.0 to 8.0) | | |
| Week 48, n=302, 298 | 13.7 (11.2 to 16.3) | 3.0 (0.4 to 5.6) | | |

Notes:

[159] - ITT-E Population

[160] - ITT-E Population

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|-----------------------------------|
| Statistical analysis description: | |
| Treatment comparison at Week 8 for the groups CAB LA+ RPV LA and current ART is presented | |
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.001 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 7.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.1 |
| upper limit | 11.7 |

| Statistical analysis title | Statistical Analysis 2 |
|---|-----------------------------------|
| Statistical analysis description: | |
| Treatment comparison Week 24 for the groups CAB LA+ RPV LA and current ART is presented | |
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.001 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 6.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.3 |
| upper limit | 10.4 |

| Statistical analysis title | Statistical Analysis 3 |
|--|-----------------------------------|
| Statistical analysis description: | |
| Treatment comparison at Week 48 for the groups CAB LA+ RPV LA and current ART is presented | |
| Comparison groups | CAB LA+RPV LA (Q4W) v Current ART |

| | |
|---|---------------------|
| Number of subjects included in analysis | 616 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.001 |
| Method | ANCOVA |
| Parameter estimate | Adjusted difference |
| Point estimate | 10.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.1 |
| upper limit | 14.4 |

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

| | |
|-----------------|---|
| End point title | Change from 4b in tolerability of injection at Week 5, 40 and 41 using numeric rating scale (NRS) within CAB LA+RPV LA arm ^[161] |
|-----------------|---|

End point description:

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

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

End point timeframe:

Weeks 4b, 5, 40 and 41

Notes:

[161] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period.

| End point values | CAB LA+RPV LA (Q4W) | | | |
|--------------------------------------|----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 278 ^[162] | | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 5 | 2.0 (± 2.94) | | | |
| Week 40 | 0.5 (± 2.79) | | | |
| Week 41 | 0.4 (± 2.83) | | | |

Notes:

[162] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

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

| | |
|-----------------|--|
| End point title | Change from Baseline in individual item scores of HIVTSQc at |
|-----------------|--|

End point description:

HIVTSQc is a 12 item questionnaire. The individual treatment change item scores on HIVTSQc scale are rated as +3 ('much more satisfied', 'much more convenient', 'much more flexible', etc.) to -3 ('much less satisfied', 'much less convenient', 'much less flexible', etc.). The higher the score, the greater the improvement in satisfaction with each aspect of treatment and the lower the score, the greater the deterioration in satisfaction with each aspect of treatment. LOCF was used as primary method of analysis. Baseline value is defined as the latest pre-treatment assessment with a non-missing value. Change from Baseline value is calculated as the value at the post-dose visit minus the Baseline value. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles). 99999 indicates data was not available due to insufficient participants.

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

End point timeframe:

Baseline and Weeks 4b, 24 and 44

| End point values | CAB LA+RPV LA (Q4W) | Current ART | | |
|--------------------------------------|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 308 ^[163] | 308 ^[164] | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Item 1; Week 4b; n=294, 0 | 0.3 (± 1.42) | 99999 (± 99999) | | |
| Item 1; Week 24; n=300, 287 | 0.4 (± 1.46) | -0.1 (± 1.04) | | |
| Item 1; Week 44; n=300, 293 | 0.5 (± 1.42) | -0.1 (± 1.21) | | |
| Item 2; Week 4b; n=295, 0 | 0.0 (± 0.60) | 99999 (± 99999) | | |
| Item 2; Week 24; n=300, 287 | 0.1 (± 0.70) | 0.0 (± 0.68) | | |
| Item 2; Week 44; n=300, 293 | 0.1 (± 0.84) | -0.1 (± 0.82) | | |
| Item 3; Week 4b; n=295, 0 | 0.4 (± 1.35) | 99999 (± 99999) | | |
| Item 3; Week 24; n=300, 288 | 0.3 (± 1.47) | 0.1 (± 1.12) | | |
| Item 3; Week 44; n=300, 294 | 0.3 (± 1.45) | 0.0 (± 1.26) | | |
| Item 4; Week 4b; n=295, 0 | 0.3 (± 1.21) | 99999 (± 99999) | | |
| Item 4; Week 24; n=300, 288 | 0.5 (± 1.29) | -0.0 (± 1.16) | | |
| Item 4; Week 44; n=300, 294 | 0.4 (± 1.30) | -0.1 (± 1.22) | | |
| Item 5; Week 4b; n=295, 0 | 0.5 (± 1.24) | 99999 (± 99999) | | |
| Item 5; Week 24; n=300, 288 | 0.8 (± 1.32) | 0.1 (± 1.31) | | |
| Item 5; Week 44; n=300, 294 | 0.8 (± 1.42) | 0.0 (± 1.37) | | |
| Item 6; Week 4b; n=294, 0 | 0.5 (± 1.63) | 99999 (± 99999) | | |
| Item 6; Week 24; n=299, 288 | 0.8 (± 1.77) | 0.2 (± 1.79) | | |
| Item 6; Week 44; n=299, 293 | 0.9 (± 1.72) | 0.2 (± 1.78) | | |
| Item 7; Week 4b; n=295, 0 | 0.2 (± 0.90) | 99999 (± 99999) | | |
| Item 7; Week 24; n=300, 288 | 0.2 (± 0.94) | 0.1 (± 1.00) | | |
| Item 7; Week 44; n=300, 294 | 0.2 (± 0.99) | 0.2 (± 1.08) | | |
| Item 8; Week 4b; n=294, 0 | 0.3 (± 1.21) | 99999 (± 99999) | | |
| Item 8; Week 24; n=299, 288 | 0.7 (± 1.27) | 0.1 (± 1.20) | | |
| Item 8; Week 44; n=299, 294 | 0.6 (± 1.31) | 0.0 (± 1.27) | | |

| | | | | |
|------------------------------|--------------|-----------------|--|--|
| Item 9; Week 4b; n=294, 0 | 0.4 (± 1.22) | 99999 (± 99999) | | |
| Item 9; Week 24; n=299, 288 | 0.6 (± 1.27) | 0.1 (± 1.20) | | |
| Item 9; Week 44; n=299, 294 | 0.5 (± 1.32) | 0.0 (± 1.25) | | |
| Item 10; Week 4b; n=293, 0 | 0.8 (± 1.44) | 99999 (± 99999) | | |
| Item 10; Week 24; n=298, 287 | 1.2 (± 1.56) | 0.3 (± 1.38) | | |
| Item 10; Week 44; n=298, 293 | 1.1 (± 1.64) | 0.2 (± 1.60) | | |
| Item 11; Week 4b; n=292, 0 | 0.4 (± 1.23) | 99999 (± 99999) | | |
| Item 11; Week 24; n=297, 287 | 0.7 (± 1.31) | 0.1 (± 1.28) | | |
| Item 11; Week 44; n=297, 293 | 0.6 (± 1.45) | 0.1 (± 1.38) | | |
| Item 12; Week 4b; n=293, 0 | 0.3 (± 1.41) | 99999 (± 99999) | | |
| Item 12; Week 24; n=298, 287 | 0.0 (± 1.52) | 0.1 (± 1.14) | | |
| Item 12; Week 44; n=298, 293 | 0.0 (± 1.58) | 0.2 (± 1.17) | | |

Notes:

[163] - ITT-E Population

[164] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

Upto Week 48

| End point values | CAB LA | RPV LA | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 0 ^[165] | 0 ^[166] | | |
| Units: Participants | | | | |

Notes:

[165] - PK Population

[166] - PK Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 52

Adverse event reporting additional description:

AEs and SAEs were collected in Safety population.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 21.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------------------|
| Reporting group title | CAB LA+RPV LA (Q4W) |
|-----------------------|---------------------|

Reporting group description:

During Maintenance phase (Day 1-Week 52), participants received oral CAB 30 milligram (mg)+RPV 25 mg once daily from Day 1 for 4 weeks. At Week 4B, the participants were given the last dose of oral CAB+RPV and the first dose of CAB LA 600 mg+RPV LA 900 mg injections within 2 hours of the final oral dose. Participants received intramuscular (IM) injections of CAB LA 400 mg and RPV LA 600 mg every four weeks (Q4W) through Week 52. After completion of Maintenance phase, participants who chose to enter Extension phase continued to receive both CAB LA and RPV LA. Participants withdrawn from study treatment who received at least one CAB LA+RPV LA injection were required to enter a 52-week long term follow-up period

| | |
|-----------------------|-------------|
| Reporting group title | Current ART |
|-----------------------|-------------|

Reporting group description:

During Maintenance phase (Day 1 - Week 52), participants continued to receive current antiretroviral therapy (ART) (protease inhibitor [PI] or integrase inhibitor [INI] or non-nucleoside reverse transcriptase inhibitor [NNRTI]) plus 2 NRTIs for 52 weeks. After completion of the Maintenance phase, participants who chose to enter the Extension phase switched to CAB LA+RPV LA

| Serious adverse events | CAB LA+RPV LA (Q4W) | Current ART | |
|---|---------------------|------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 13 / 308 (4.22%) | 14 / 308 (4.55%) | |
| number of deaths (all causes) | 0 | 1 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papillary thyroid cancer | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Seminoma | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Liver function test abnormal | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (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 | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye injury | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Overdose | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Skull fracture | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion missed | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion spontaneous | | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| 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 discomfort | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Colitis | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 2 / 308 (0.65%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular injury | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (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 | | | |
| Hepatitis A | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute hepatitis B | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal abscess | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis Escherichia coli | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver abscess | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 308 (0.00%) | 1 / 308 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 1 / 308 (0.32%) | 0 / 308 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| 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 (Q4W) | Current ART | |
|---|--------------------------------|--------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 263 / 308 (85.39%) | 117 / 308 (37.99%) | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 34 / 308 (11.04%) | 17 / 308 (5.52%) | |
| occurrences (all) | 48 | 19 | |
| General disorders and administration site conditions | | | |
| Injection site pain | | | |
| subjects affected / exposed | 231 / 308 (75.00%) | 0 / 308 (0.00%) | |
| occurrences (all) | 1208 | 0 | |
| Injection site nodule | | | |
| subjects affected / exposed | 37 / 308 (12.01%) | 0 / 308 (0.00%) | |
| occurrences (all) | 54 | 0 | |
| Injection site induration | | | |
| subjects affected / exposed | 30 / 308 (9.74%) | 0 / 308 (0.00%) | |
| occurrences (all) | 54 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 21 / 308 (6.82%) | 9 / 308 (2.92%) | |
| occurrences (all) | 29 | 9 | |
| Fatigue | | | |
| subjects affected / exposed | 22 / 308 (7.14%) | 6 / 308 (1.95%) | |
| occurrences (all) | 29 | 9 | |
| Injection site swelling | | | |
| subjects affected / exposed | 23 / 308 (7.47%) | 0 / 308 (0.00%) | |
| occurrences (all) | 48 | 0 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 22 / 308 (7.14%) | 15 / 308 (4.87%) | |
| occurrences (all) | 24 | 17 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 16 / 308 (5.19%) | 14 / 308 (4.55%) | |
| occurrences (all) | 20 | 16 | |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|-------------------------|-------------------------|--|
| Back pain subjects affected / exposed occurrences (all) | 20 / 308 (6.49%) 22 | 10 / 308 (3.25%) 12 | |
| Infections and infestations | | | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 52 / 308 (16.88%) 87 | 42 / 308 (13.64%) 58 | |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 32 / 308 (10.39%) 48 | 25 / 308 (8.12%) 30 | |
| Influenza subjects affected / exposed occurrences (all) | 17 / 308 (5.52%) 19 | 14 / 308 (4.55%) 15 | |
| Respiratory tract infection viral subjects affected / exposed occurrences (all) | 11 / 308 (3.57%) 12 | 17 / 308 (5.52%) 23 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|--|
| 16 September 2016 | Amendment No.1: requirements for South Korea; update I/E criteria age per local regulatory; add IP labels to Appendix 8. |
| 02 November 2016 | Amendment No.2: requirements for Sweden; protocol details and clarifications requested by MPA. |
| 13 December 2016 | Amendment No.3: contact MM if rash occurs during OLI period; add lipid objective and endpoint; IP dosing at Day 1 visit clarity; allow serum pregnancy testing instead of urine testing when not available; CAB, RPV exposure may persist for more than 1 year after IM injections; use of HAART for 1 year after last CAB+RPV injection, females use adequate contraception for 1 year after last CAB+RPV injection; treatment with glucocorticoids up to 21 days; definition of change in ART regimen for I/E criteria; contact MM upon serofast RPR result for screening syphilis test; remove requirement to record frequency of IP taken and treatment delays or dose reductions of IP in eCRF; indicate drugs known to cause TdP to be used with caution with RPV; remove limits on duration of topical imiquimod; clarity on reflexive testing for HBV DNA for participants with + anti-HBc, - HBsAg, - anti-HBs results; temperature collection to T&E table; site plans for managing risks for suicide related events; PK sample window collection clarity; PRO timings clarification; prohibited meds clarification; remove collection of pregnancy information for female partners of male study participants; details of injection device for IM administration collected within eCRF; local labs approved by MM for eligibility in special circumstances; screening HLA-B*5701 result is not required for eligibility status. |
| 07 November 2017 | Amendment No.4: potential rollover of participants to study 207966; snapshot virologic response replaced with proportion of participants with plasma HIV-1 RNA < 50 c/mL over time; exploratory analyses evaluating virologic, immunologic responses in treatment arms limited to Week 48 analysis; pregnancy and follow-up pregnancy event form report timing updated; updated references for CAB, RPV IBs. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported