



## Clinical trial results:

**A Phase IIIb, open-label, hybrid type III trial evaluating implementation strategies for long-acting cabotegravir plus long-acting rilpivirine every two months in HIV-1 infected, virologically suppressed adults in select European healthcare settings**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2020-000424-19 |
| Trial protocol           | FR DE NL BE    |
| Global end of trial date |                |

### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1            |
| This version publication date  | 28 March 2023 |
| First version publication date | 28 March 2023 |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 213199 |
|-----------------------|--------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04399551 |
| WHO universal trial number (UTN)   | -           |

Notes:

### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | ViiV Healthcare  |
| Sponsor organisation address | 980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS               |
| Public contact               | GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact           | GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com |

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

|  |               |
|--|---------------|
| Analysis stage                                       | Interim       |
| Date of interim/final analysis                       | 07 March 2022 |
| Is this the analysis of the primary completion data? | Yes           |
| Primary completion date                              | 07 March 2022 |
| Global end of trial reached?                         | No            |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate acceptability, appropriateness, and feasibility of long-acting cabotegravir plus long-acting rilpivirine on the basis of staff study participants ratings.

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

|   |                   |
|---|-------------------|
| Actual start date of recruitment                          | 28 September 2020 |
| Long term follow-up planned                               | No                |
| Independent data monitoring committee (IDMC) involvement? | No                |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                 |
|--------------------------------------|-----------------|
| Country: Number of subjects enrolled | Belgium: 71     |
| Country: Number of subjects enrolled | France: 177     |
| Country: Number of subjects enrolled | Germany: 54     |
| Country: Number of subjects enrolled | Netherlands: 39 |
| Country: Number of subjects enrolled | Spain: 96       |
| Worldwide total number of subjects   | 437             |
| EEA total number of subjects         | 437             |

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)                      | 427 |
| From 65 to 84 years                       | 10  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

A total of 437 patient study participants (PSPs) [people living with HIV] were enrolled. 430 PSP received study treatment and were included in the safety population. Staff Study Participants (SSP) (HIV care providers, nurses/staff performing injections administrators/clinic managers) are not counted in the enrolment.

### Pre-assignment

Screening details:

SSP were randomized based on implementation strategy - Enhanced (Arm-E) and Standard (Arm -S). SSP provided input through surveys, semi-structured interviews and a selected group from the enhanced arm (Arm-E) participated in facilitation calls.

### Period 1

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

### Arms

|           |                            |
|-----------|----------------------------|
| Arm title | Patient Study Participants |
|-----------|----------------------------|

Arm description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

|  |              |
|--|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | CAB OLI      |
| Investigational medicinal product code |              |
| Other name                             |              |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

Oral cabotegravir (CAB) was administered as a 30 milligram (mg) tablet, taken once daily with food from Day 1 to Month 1.

|  |          |
|--|----------|
| Investigational medicinal product name | RPV OLI  |
| Investigational medicinal product code |          |
| Other name                             |          |
| Pharmaceutical forms                   | Tablet   |
| Routes of administration               | Oral use |

Dosage and administration details:

Oral rilpivirine (RPV) was administered as a 25 mg tablet, taken once daily with food from Day 1 to Month 1.

|  |                   |
|--|-------------------|
| Investigational medicinal product name | RPV LA            |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Long-acting rilpivirine (RPV LA) 900 mg (3 mL) was administered via intramuscular injection by a healthcare professional.

|  |                   |
|--|-------------------|
| Investigational medicinal product name | CAB LA            |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Long-acting cabotegravir (CAB LA) 600 mg (3 mL) was administered via intramuscular injection by a healthcare professional.

| <b>Number of subjects in period 1<sup>[1]</sup></b> | <b>Patient Study Participants</b> |
|---|-----------------------------------|
| Started   | 430                               |
| Completed   | 306                               |
| Not completed                                       | 124                               |
| Consent withdrawn by subject                        | 6                                 |
| Physician decision                                  | 3                                 |
| Adverse event, non-fatal                            | 12                                |
| Protocol Deviation                                  | 2                                 |
| Ongoing   | 100                               |
| Lost to follow-up                                   | 1                                 |

Notes:

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

Justification: A total of 437 participants were enrolled and 430 participants received study treatment and were included in the safety population.

## Baseline characteristics

### Reporting groups

|   |                            |
|---|----------------------------|
| Reporting group title   | Patient Study Participants |
| Reporting group description:  |                            |
| PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route. |                            |

| Reporting group values                             | Patient Study Participants | Total |  |
|--|----------------------------|-------|--|
| Number of subjects                                 | 430                        | 430   |  |
| Age categorical                                    |                            |       |  |
| Units: Subjects                                    |                            |       |  |
| In utero   | 0                          | 0     |  |
| Preterm newborn infants (gestational age < 37 wks) | 0                          | 0     |  |
| Newborns (0-27 days)                               | 0                          | 0     |  |
| Infants and toddlers (28 days-23 months)           | 0                          | 0     |  |
| Children (2-11 years)                              | 0                          | 0     |  |
| Adolescents (12-17 years)                          | 0                          | 0     |  |
| Adults (18-64 years)                               | 420                        | 420   |  |
| From 65-84 years                                   | 10                         | 10    |  |
| 85 years and over                                  | 0                          | 0     |  |
| Age Continuous                                     |                            |       |  |
| Units: Years                                       |                            |       |  |
| arithmetic mean                                    | 44.2                       |       |  |
| standard deviation                                 | ± 10.13                    | -     |  |
| Sex: Female, Male                                  |                            |       |  |
| Units: Participants                                |                            |       |  |
| Female   | 115                        | 115   |  |
| Male   | 315                        | 315   |  |
| Race/Ethnicity, Customized                         |                            |       |  |
| Units: Subjects                                    |                            |       |  |
| American Indian Or Alaska Native                   | 7                          | 7     |  |
| Asian  | 9                          | 9     |  |
| Black Or African American                          | 76                         | 76    |  |
| White  | 336                        | 336   |  |
| Multiple   | 2                          | 2     |  |

### Subject analysis sets

|                            |  |
|----------------------------|--|
| Subject analysis set title | Staff Study Participants – Enhanced Implementation Arm |
| Subject analysis set type  | Full analysis  |

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, SWAT meeting with sponsor team and principal clinic stakeholders, on-demand SWAT meeting, monthly

continuous quality improvement (CQI) calls, face-to-face injection training, monthly FRAME assessment, access to patient and HCP level toolkit and CAB + RPV medical lead site visit.

|                            |  |
|----------------------------|--|
| Subject analysis set title | Staff Study Participants – Standard Implementation Arm |
| Subject analysis set type  | Full analysis  |

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, CAB + RPV medical lead site visit, access to patient and HCP level toolkit, virtual injection training and monthly FRAME assessment.

|                            |                                |
|----------------------------|--------------------------------|
| Subject analysis set title | Staff Study Participants (SSP) |
| Subject analysis set type  | Full analysis                  |

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.

|                            |                          |
|----------------------------|--------------------------|
| Subject analysis set title | Staff Study Participants |
| Subject analysis set type  | Full analysis            |

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.

|                            |  |
|----------------------------|--|
| Subject analysis set title | Staff Study Participants – Standard Implementation Arm |
| Subject analysis set type  | Full analysis  |

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, CAB + RPV medical lead site visit, access to patient and HCP level toolkit, virtual injection training and monthly FRAME assessment.

|                            |                                |
|----------------------------|--------------------------------|
| Subject analysis set title | Staff Study Participants (SSP) |
| Subject analysis set type  | Full analysis                  |

Subject analysis set description:

SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.

|                            |                                   |
|----------------------------|-----------------------------------|
| Subject analysis set title | Patient Study Participants (PSPs) |
| Subject analysis set type  | Full analysis                     |

Subject analysis set description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

|                            |                                   |
|----------------------------|-----------------------------------|
| Subject analysis set title | Patient Study Participants (PSPs) |
| Subject analysis set type  | Safety analysis                   |

Subject analysis set description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

| <b>Reporting group values</b>   | Staff Study<br>Participants –<br>Enhanced<br>Implementation Arm | Staff Study<br>Participants –<br>Standard<br>Implementation Arm | Staff Study<br>Participants (SSP) |
|---|---|---|-----------------------------------|
| Number of subjects  | 34  | 36  | 62                                |
| Age categorical<br>Units: Subjects  |   |   |                                   |
| In utero<br>Preterm newborn infants<br>(gestational age < 37 wks)<br>Newborns (0-27 days)<br>Infants and toddlers (28 days-23<br>months)<br>Children (2-11 years)<br>Adolescents (12-17 years)<br>Adults (18-64 years)<br>From 65-84 years<br>85 years and over |   |   |                                   |
| Age Continuous<br>Units: Years<br>arithmetic mean<br>standard deviation   | ±   | ±   | ±                                 |
| Sex: Female, Male<br>Units: Participants  |   |   |                                   |
| Female<br>Male  |   |   |                                   |
| Race/Ethnicity, Customized<br>Units: Subjects   |   |   |                                   |
| American Indian Or Alaska Native<br>Asian<br>Black Or African American<br>White<br>Multiple   |   |   |                                   |

| <b>Reporting group values</b>   | Staff Study<br>Participants | Staff Study<br>Participants –<br>Standard<br>Implementation Arm | Staff Study<br>Participants (SSP) |
|---|-----------------------------|---|-----------------------------------|
| Number of subjects  | 69                          | 35  | 18                                |
| Age categorical<br>Units: Subjects  |                             |   |                                   |
| In utero<br>Preterm newborn infants<br>(gestational age < 37 wks)<br>Newborns (0-27 days)<br>Infants and toddlers (28 days-23<br>months)<br>Children (2-11 years)<br>Adolescents (12-17 years)<br>Adults (18-64 years)<br>From 65-84 years<br>85 years and over |                             |   |                                   |

|   |       |       |             |
|---|-------|-------|-------------|
| Age Continuous<br>Units: Years<br>arithmetic mean<br>standard deviation                     | $\pm$ | $\pm$ | 23<br>$\pm$ |
| Sex: Female, Male<br>Units: Participants  |       |       |             |
| Female<br>Male  |       |       |             |
| Race/Ethnicity, Customized<br>Units: Subjects   |       |       |             |
| American Indian Or Alaska Native<br>Asian<br>Black Or African American<br>White<br>Multiple |       |       |             |

| <b>Reporting group values</b>   | Patient Study<br>Participants (PSPs) | Patient Study<br>Participants (PSPs) |  |
|---|--------------------------------------|--------------------------------------|--|
| Number of subjects  | 110                                  | 430                                  |  |
| Age categorical<br>Units: Subjects  |                                      |                                      |  |
| In utero<br>Preterm newborn infants<br>(gestational age < 37 wks)<br>Newborns (0-27 days)<br>Infants and toddlers (28 days-23<br>months)<br>Children (2-11 years)<br>Adolescents (12-17 years)<br>Adults (18-64 years)<br>From 65-84 years<br>85 years and over |                                      |                                      |  |
| Age Continuous<br>Units: Years<br>arithmetic mean<br>standard deviation   | $\pm$                                | 93<br>$\pm$                          |  |
| Sex: Female, Male<br>Units: Participants  |                                      |                                      |  |
| Female<br>Male  |                                      |                                      |  |
| Race/Ethnicity, Customized<br>Units: Subjects   |                                      |                                      |  |
| American Indian Or Alaska Native<br>Asian<br>Black Or African American<br>White<br>Multiple   |                                      |                                      |  |



## End points

### End points reporting groups

|  |  |
|--|--|
| Reporting group title  | Patient Study Participants                             |
| Reporting group description:<br>PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.  |  |
| Subject analysis set title   | Staff Study Participants – Enhanced Implementation Arm |
| Subject analysis set type  | Full analysis  |
| Subject analysis set description:<br>SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, SWAT meeting with sponsor team and principal clinic stakeholders, on-demand SWAT meeting, monthly continuous quality improvement (CQI) calls, face-to-face injection training, monthly FRAME assessment, access to patient and HCP level toolkit and CAB + RPV medical lead site visit. |  |
| Subject analysis set title   | Staff Study Participants – Standard Implementation Arm |
| Subject analysis set type  | Full analysis  |
| Subject analysis set description:<br>SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, CAB + RPV medical lead site visit, access to patient and HCP level toolkit, virtual injection training and monthly FRAME assessment.  |  |
| Subject analysis set title   | Staff Study Participants (SSP)                         |
| Subject analysis set type  | Full analysis  |
| Subject analysis set description:<br>SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.  |  |
| Subject analysis set title   | Staff Study Participants                               |
| Subject analysis set type  | Full analysis  |
| Subject analysis set description:<br>SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.  |  |
| Subject analysis set title   | Staff Study Participants – Standard Implementation Arm |
| Subject analysis set type  | Full analysis  |
| Subject analysis set description:<br>SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input using surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections. This arm contains components like investigator meeting, CAB + RPV medical lead site visit, access to patient and HCP level toolkit, virtual injection training and monthly FRAME assessment.  |  |
| Subject analysis set title   | Staff Study Participants (SSP)                         |
| Subject analysis set type  | Full analysis  |
| Subject analysis set description:<br>SSPs included HIV care providers (HCPs), nurses/staff performing CAB + RPV LA injections, and administrators/clinic managers at each investigational site. They provided input through the use of surveys, semi structured interviews (SSI) and via monthly facilitation calls. SSPs did not receive oral lead-in medication or CAB+RPV LA injections.  |  |

|                            |                                   |
|----------------------------|-----------------------------------|
| Subject analysis set title | Patient Study Participants (PSPs) |
| Subject analysis set type  | Full analysis                     |

Subject analysis set description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

|                            |                                   |
|----------------------------|-----------------------------------|
| Subject analysis set title | Patient Study Participants (PSPs) |
| Subject analysis set type  | Safety analysis                   |

Subject analysis set description:

PSPs received one tablet of cabotegravir (CAB) 30 milligrams (mg) + rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

### Primary: Change from Baseline in Acceptability of Implementation Measure (AIM-Imp) Score in SSP at Month 12

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Acceptability of Implementation Measure (AIM-Imp) Score in SSP at Month 12 <sup>[1]</sup> |
|-----------------|---|

End point description:

The AIM-Imp was designed to assess the acceptability of an implementation process (i.e., perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable or satisfactory). The measure consists of four items/statements (1. The implementation support thus far meets my approval 2. The implementation support thus far is appealing to me 3. I like the implementation support I have received 4. I welcome implementation support for the CAB + RPV injection treatment), each with a five-point rating scale (1=completely disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=completely agree). The mean score ranges from 1 to 5 with 1 indicating the least acceptability and 5 the most acceptability. Analysis was performed on Full analysis set (FAS), which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Baseline (Month 1) and Month 12

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

| End point values                     | Staff Study Participants – Enhanced Implementation Arm | Staff Study Participants – Standard Implementation Arm |  |  |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Subject analysis set                                   | Subject analysis set                                   |  |  |
| Number of subjects analysed          | 34   | 36   |  |  |
| Units: Scores on a scale             |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Baseline (Month 1)                   | 3.8 (± 0.76)   | 3.9 (± 0.75)   |  |  |
| Month 12                             | 0.28 (± 0.828)   | 0.33 (± 0.666)   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: Change from Baseline in Implementation Appropriateness Measure (IAM-

## Imp) Score in SSPs at Month 12

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Implementation Appropriateness Measure (IAM-Imp) Score in SSPs at Month 12 <sup>[2]</sup> |
|-----------------|---|

### End point description:

The IAM-Imp is designed to assess the appropriateness of an implementation process (i.e., the perceived fit, relevance, or compatibility of the innovation for a given practice setting, provider, or consumer, and the perceived fit of the innovation to address a particular issue or problem). The IAM-Imp is a four-item/statement measure (1. The implementation support thus far seems fitting 2. The implementation support seems suitable for using the CAB + RPV injection treatment 3. The implementation support seems applicable for the CAB + RPV injection treatment 4. The implementation support seems like a good match) with a five-point rating scale (1=completely disagree, 2=disagree, 3 = neither agree nor disagree, 4 = agree, and 5 = completely agree). The mean score ranges from 1 to 5 with 1 indicating the least appropriateness and 5 the most appropriateness. Analysis was performed on FAS population.

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

### End point timeframe:

Baseline (Month 1) and Month 12

### Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

| End point values                     | Staff Study Participants – Enhanced Implementation Arm | Staff Study Participants – Standard Implementation Arm |  |  |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Subject analysis set                                   | Subject analysis set                                   |  |  |
| Number of subjects analysed          | 34   | 36   |  |  |
| Units: Scores on a scale             |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Baseline (Month 1)                   | 3.8 (± 0.78)   | 3.9 (± 0.78)   |  |  |
| Month 12                             | 0.22 (± 0.740)   | 0.31 (± 0.729)   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Change from Baseline in Feasibility of Implementation Measure (FIM-Imp) Score at Month 12

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Feasibility of Implementation Measure (FIM-Imp) Score at Month 12 <sup>[3]</sup> |
|-----------------|--|

### End point description:

The FIM-Imp was a four-item/statement (1. The implementation support seems implementable in our clinic/practice 2. The implementation support seems possible in our clinic/practice 3. The implementation support seems doable in our clinic/practice 4. The implementation support seems easy to use in our clinic/practice) and was measured on a five-point rating scale (1 = completely disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, and 5 = completely agree). The mean score ranges from 1 to 5 with 1 indicating the least feasibility and 5 the most feasibility.

Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

### End point timeframe:

Baseline (Month 1) and Month 12

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

| End point values                     | Staff Study Participants – Enhanced Implementation Arm | Staff Study Participants – Standard Implementation Arm |  |  |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Subject analysis set                                   | Subject analysis set                                   |  |  |
| Number of subjects analysed          | 34   | 36   |  |  |
| Units: Scores on a scale             |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Baseline (Month 1)                   | 4.0 (± 0.66)   | 4.0 (± 0.64)   |  |  |
| Month 12                             | 0.06 (± 1.047)   | 0.34 (± 0.773)   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Staff Study Participants that discussed Facilitators for Acceptability Assessed via Semi Structured Interviews (SSIs)

|                 |  |
|-----------------|--|
| End point title | Number of Staff Study Participants that discussed Facilitators for Acceptability Assessed via Semi Structured Interviews (SSIs) <sup>[4]</sup> |
|-----------------|--|

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the acceptability from the SSPs' perspective. The results for facilitators that are integral to successful implementation are presented. Patient Perspective was abbreviated as [PP]. Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to 12 Months

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

| End point values                                  | Staff Study Participants (SSP) |  |  |  |
|---|--------------------------------|--|--|--|
| Subject group type                                | Subject analysis set           |  |  |  |
| Number of subjects analysed                       | 62                             |  |  |  |
| Units: Participants                               |                                |  |  |  |
| Positive opinion                                  | 56                             |  |  |  |
| Treatment and Implementation better than expected | 18                             |  |  |  |
| Patient satisfaction                              | 30                             |  |  |  |

|   |    |  |  |  |
|---|----|--|--|--|
| [PP] Not worrying about taking medication   | 14 |  |  |  |
| Discreet treatment                          | 11 |  |  |  |
| [PP] Not being reminded about HIV           | 11 |  |  |  |
| Patient travel facilitation                 | 10 |  |  |  |
| Patient adherence                           | 8  |  |  |  |
| Innovative treatment                        | 8  |  |  |  |
| Medication efficacy                         | 8  |  |  |  |
| [PP] Gaining a sense of freedom/liberation  | 6  |  |  |  |
| [PP]Not having to take treatment every day  | 6  |  |  |  |
| New treatment option                        | 6  |  |  |  |
| Patient quality of life improvement         | 6  |  |  |  |
| No resistance to implementing CAB+RPV LA    | 27 |  |  |  |
| Administration in Other Clinical Setting    | 6  |  |  |  |
| Home Administration by HCP-Patient Interest | 16 |  |  |  |
| Self-injection-Patient interest             | 12 |  |  |  |
| Information on medication characteristics   | 8  |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Staff Study Participants that discussed Barriers for Acceptability Assessed via SSIs

|                 |   |
|-----------------|---|
| End point title | Number of Staff Study Participants that discussed Barriers for Acceptability Assessed via SSIs <sup>[5]</sup> |
|-----------------|---|

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the acceptability from the SSPs' perspective. The results for barriers that are integral to successful implementation are presented.

Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to 12 Months

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

| End point values                               | Staff Study Participants (SSP) |  |  |  |
|--|--------------------------------|--|--|--|
| Subject group type                             | Subject analysis set           |  |  |  |
| Number of subjects analysed                    | 62                             |  |  |  |
| Units: Participants                            |                                |  |  |  |
| Medication tolerability and side effects       | 29                             |  |  |  |
| Injection side effects                         | 6                              |  |  |  |
| Home Administration by HCP-No patient interest | 9                              |  |  |  |
| Self-injection-Injection site                  | 7                              |  |  |  |
| Self-injection-Adherence                       | 6                              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Staff Study Participants that discussed Facilitators for Appropriateness Assessed via SSIs

|                 |   |
|-----------------|---|
| End point title | Number of Staff Study Participants that discussed Facilitators for Appropriateness Assessed via SSIs <sup>[6]</sup> |
|-----------------|---|

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the appropriateness from the SSPs' perspective. The results for facilitators that are integral to successful implementation are presented.

Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to 12 Months

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

| End point values                         | Staff Study Participants (SSP) |  |  |  |
|--|--------------------------------|--|--|--|
| Subject group type                       | Subject analysis set           |  |  |  |
| Number of subjects analysed              | 62                             |  |  |  |
| Units: Participants                      |                                |  |  |  |
| Not being reminded of HIV status         | 15                             |  |  |  |
| Discreet treatment                       | 14                             |  |  |  |
| Sense of freedom/liberation              | 10                             |  |  |  |
| Travel facilitation                      | 10                             |  |  |  |
| No need to think/worry about pills       | 9                              |  |  |  |
| Adherent patients                        | 30                             |  |  |  |
| No particular patient profile            | 13                             |  |  |  |
| Patients non-adherent to oral medication | 13                             |  |  |  |

|   |    |  |  |  |
|---|----|--|--|--|
| Patients seeking discreet treatment       | 10 |  |  |  |
| Patients with non-resistant HIV           | 10 |  |  |  |
| Patients seeking to change oral treatment | 8  |  |  |  |
| Young patients                            | 8  |  |  |  |
| Frequently travelling patients            | 6  |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Staff Study Participants that discussed Barriers for Appropriateness Assessed via SSIs

|                 |   |
|-----------------|---|
| End point title | Number of Staff Study Participants that discussed Barriers for Appropriateness Assessed via SSIs <sup>[7]</sup> |
|-----------------|---|

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the appropriateness from the SSPs' perspective. The results for barriers that are integral to successful implementation are presented.

Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to 12 Months

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

| End point values            | Staff Study Participants (SSP) |  |  |  |
|-----------------------------|--------------------------------|--|--|--|
| Subject group type          | Subject analysis set           |  |  |  |
| Number of subjects analysed | 62                             |  |  |  |
| Units: Participants         | 7                              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Staff Study Participants that discussed Facilitators for Feasibility Assessed via SSIs

|                 |   |
|-----------------|---|
| End point title | Number of Staff Study Participants that discussed Facilitators for Feasibility Assessed via SSIs <sup>[8]</sup> |
|-----------------|---|

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to

facilitate discussions on the feasibility from the SSPs' perspective. The results for facilitators that are integral to successful implementation are presented.

Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to 12 Months

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

| End point values                                 | Staff Study Participants (SSP) |  |  |  |
|--|--------------------------------|--|--|--|
| Subject group type                               | Subject analysis set           |  |  |  |
| Number of subjects analysed                      | 62                             |  |  |  |
| Units: Participants                              |                                |  |  |  |
| Medication delivery from pharmacy                | 15                             |  |  |  |
| Additional staff                                 | 13                             |  |  |  |
| Room and/or space                                | 13                             |  |  |  |
| Training   | 11                             |  |  |  |
| Responsibilities and/or multitasking             | 10                             |  |  |  |
| Specific time and/or day for injection visits    | 9                              |  |  |  |
| Scheduling strategies                            | 8                              |  |  |  |
| Additional refrigerator                          | 7                              |  |  |  |
| Clinic hours                                     | 7                              |  |  |  |
| Non-covid Oral bridging                          | 7                              |  |  |  |
| Staff characteristics                            | 14                             |  |  |  |
| No supplemental materials Developed              | 11                             |  |  |  |
| Supplemental materials Developed                 | 8                              |  |  |  |
| No staffing and workload issues in the past      | 19                             |  |  |  |
| No current staffing and workload issues          | 13                             |  |  |  |
| No issues designated space availability          | 34                             |  |  |  |
| No current issues with space availability        | 7                              |  |  |  |
| No coordination with pharmacy issues in the past | 40                             |  |  |  |
| No issues with medication supply                 | 31                             |  |  |  |
| No current issues with medication supply         | 7                              |  |  |  |
| No issues with clinic working hours in the past  | 41                             |  |  |  |
| ViiV supportive in implementation                | 55                             |  |  |  |
| Administration in General Practitioner office    | 13                             |  |  |  |
| Administration in healthcare centers             | 11                             |  |  |  |
| Administration in private practice               | 6                              |  |  |  |
| Injection training                               | 10                             |  |  |  |



## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Staff Study Participants that discussed Barriers for Feasibility Assessed via SSIs

|                 |   |
|-----------------|---|
| End point title | Number of Staff Study Participants that discussed Barriers for Feasibility Assessed via SSIs <sup>[9]</sup> |
|-----------------|---|

End point description:

A semi-structured interview guide was designed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the feasibility from the SSPs' perspective. The results for barriers that are integral to successful implementation are presented.

Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to 12 Months

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The design does not have any statistical hypothesis. Hence statistical data is not presented.

| End point values                               | Staff Study Participants (SSP) |  |  |  |
|--|--------------------------------|--|--|--|
| Subject group type                             | Subject analysis set           |  |  |  |
| Number of subjects analysed                    | 62                             |  |  |  |
| Units: Participants                            |                                |  |  |  |
| Staffing and workload issues                   | 15                             |  |  |  |
| Appointment duration                           | 15                             |  |  |  |
| Appointment scheduling                         | 9                              |  |  |  |
| Number of visits                               | 7                              |  |  |  |
| Room and/or space issues                       | 6                              |  |  |  |
| Staffing and workload issues in the past       | 32                             |  |  |  |
| Current staffing and workload issues           | 11                             |  |  |  |
| Issues with space availability in the past     | 20                             |  |  |  |
| Current issues with space availability         | 12                             |  |  |  |
| Coordination with pharmacy issues in the past  | 13                             |  |  |  |
| Current coordination with pharmacy issues      | 6                              |  |  |  |
| Issues with supply and storage in the past     | 12                             |  |  |  |
| Issues with clinic working hours in the past   | 6                              |  |  |  |
| Medication collection, cold chain, and storage | 6                              |  |  |  |
| Injection technique                            | 21                             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Modifications Reported by SSPs Assessed via FRAME-IS

|                 |  |
|-----------------|--|
| End point title | Number of Modifications Reported by SSPs Assessed via FRAME-IS |
|-----------------|--|

End point description:

The Framework for Reporting Adaptations and Modifications to Evidence-based interventions – Implementation Strategies (FRAME-IS) was a seven-question measure (contained both open and closed categorical questions) used to record details the modifications made to the implementation of the CAB LA + RPV LA injection treatment procedures.

Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12

| End point values               | Staff Study Participants – Enhanced Implementation Arm | Staff Study Participants – Standard Implementation Arm |  |  |
|--------------------------------|--|--|--|--|
| Subject group type             | Subject analysis set                                   | Subject analysis set                                   |  |  |
| Number of subjects analysed    | 34   | 35   |  |  |
| Units: Number of Modifications |  |  |  |  |
| Month 2                        | 15   | 7  |  |  |
| Month 3                        | 10   | 2  |  |  |
| Month 4                        | 5  | 2  |  |  |
| Month 5                        | 1  | 1  |  |  |
| Month 6                        | 3  | 0  |  |  |
| Month 7                        | 4  | 0  |  |  |
| Month 8                        | 0  | 0  |  |  |
| Month 9                        | 3  | 0  |  |  |
| Month 10                       | 0  | 0  |  |  |
| Month 11                       | 3  | 1  |  |  |
| Month 12                       | 0  | 1  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Plan, Do, Study, Act (PDSA) Cycles Developed During the Continuous Quality Improvement (CQI) Calls Course

|                 |   |
|-----------------|---|
| End point title | Number of Plan, Do, Study, Act (PDSA) Cycles Developed During the Continuous Quality Improvement (CQI) Calls Course |
|-----------------|---|

End point description:

CQI were a 60 minutes calls involved working through a plan to address the identified barriers, optimize processes, and evaluate these efforts. This process of addressing barriers was guided by a series of Plan, Do, Study, Act (PDSA) cycles. Number of PDSA cycles developed are presented.

Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at

least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Month 2 to Month 7   |           |

| End point values            | Staff Study Participants (SSP) |  |  |  |
|-----------------------------|--------------------------------|--|--|--|
| Subject group type          | Subject analysis set           |  |  |  |
| Number of subjects analysed | 18                             |  |  |  |
| Units: Cycles               | 23                             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants Spending Average Time in the Clinic/Practice for Each Injection Visit Assessed via Questionnaire

|                 |   |
|-----------------|---|
| End point title | Number of Participants Spending Average Time in the Clinic/Practice for Each Injection Visit Assessed via Questionnaire |
|-----------------|---|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The average time was categorized as: Up to 20 Minutes, Up to 40 Minutes, Up to 60 Minutes, Up to 90 Minutes, More than 90 Minutes and missing. Missing include participants who did not provide a response for the question. Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Up to Month 12       |           |

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Up to 20 Minutes            | 71                         |  |  |  |
| Up to 40 Minutes            | 134                        |  |  |  |
| Up to 60 Minutes            | 99                         |  |  |  |
| Up to 90 Minutes            | 48                         |  |  |  |
| More than 90 Minutes        | 19                         |  |  |  |
| Missing                     | 8                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants Spending Average Time in an Exam Room Waiting for a Nurse (or Other Healthcare Provider) to Get the Injection Administered Assessed via Questionnaire

|                 |  |
|-----------------|--|
| End point title | Number of Participants Spending Average Time in an Exam Room Waiting for a Nurse (or Other Healthcare Provider) to Get the Injection Administered Assessed via Questionnaire |
|-----------------|--|

#### End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The average time was categorized as: Up to 10 Minutes, 11-20 Minutes, 21-30 Minutes, 31-45 Minutes, More than 45 Minutes and Missing. Missing include participants who did not provide a response for the question. Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Up to 10 Minutes            | 190                        |  |  |  |
| 11-20 Minutes               | 100                        |  |  |  |
| 21-30 Minutes               | 54                         |  |  |  |
| 31-45 Minutes               | 25                         |  |  |  |
| More than 45 Minutes        | 5                          |  |  |  |
| Missing                     | 5                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants with the Acceptability with the Amount of Time Spent in The Clinic/Practice for Each Injection Visit Assessed via Questionnaire

|                 |  |
|-----------------|--|
| End point title | Number of Participants with the Acceptability with the Amount of Time Spent in The Clinic/Practice for Each Injection Visit Assessed via Questionnaire |
|-----------------|--|

---

**End point description:**

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The acceptability was categorized as extremely acceptable, very acceptable, somewhat acceptable, a little acceptable, not at all acceptable and missing. Missing include participants who did not provide a response for the question. Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

---

End point timeframe:

Month 12

---

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Extremely acceptable        | 140                        |  |  |  |
| Very acceptable             | 151                        |  |  |  |
| Somewhat acceptable         | 72                         |  |  |  |
| A little acceptable         | 11                         |  |  |  |
| Not at all acceptable       | 0                          |  |  |  |
| Missing                     | 5                          |  |  |  |

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**Statistical analyses**

No statistical analyses for this end point

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**Secondary: Number of Participants with Acceptability to Come to the Clinic/Practice Every 2 Months for the Injection Visit Assessed via Questionnaire**

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|                 |  |
|-----------------|--|
| End point title | Number of Participants with Acceptability to Come to the Clinic/Practice Every 2 Months for the Injection Visit Assessed via Questionnaire |
|-----------------|--|

---

**End point description:**

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The acceptability was categorized as extremely acceptable, very acceptable, somewhat acceptable, a little acceptable, not at all acceptable and missing. Missing include participants who did not provide a response for the question. Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

---

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

---

End point timeframe:

Month 12

---

|                             |                            |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| <b>End point values</b>     | Patient Study Participants |  |  |  |
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Extremely acceptable        | 163                        |  |  |  |
| Very acceptable             | 154                        |  |  |  |
| Somewhat acceptable         | 51                         |  |  |  |
| A little acceptable         | 6                          |  |  |  |
| Not at all acceptable       | 0                          |  |  |  |
| Missing                     | 5                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants Taking Time Off from Work to Attend Appointment Assessed via Questionnaire

|                 |   |
|-----------------|---|
| End point title | Number of Participants Taking Time Off from Work to Attend Appointment Assessed via Questionnaire |
|-----------------|---|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The time off responses were categorized as Whole day annual leave, Half day annual leave, Whole day sick leave, Half day sick leave, Whole day unpaid, Half day unpaid, Other, No time off and missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

|                                     |                            |  |  |  |
|-------------------------------------|----------------------------|--|--|--|
| <b>End point values</b>             | Patient Study Participants |  |  |  |
| Subject group type                  | Reporting group            |  |  |  |
| Number of subjects analysed         | 379                        |  |  |  |
| Units: Participants                 |                            |  |  |  |
| Whole day annual leave              | 27                         |  |  |  |
| Half day annual leave               | 20                         |  |  |  |
| Whole day sick leave                | 5                          |  |  |  |
| Half day sick leave                 | 3                          |  |  |  |
| Whole day unpaid                    | 9                          |  |  |  |
| Half day unpaid                     | 20                         |  |  |  |
| Other                               | 64                         |  |  |  |
| No, I did not have to take time off | 222                        |  |  |  |
| Missing                             | 9                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants who Seek Additional Care from a Dependent to Attend Appointment Assessed via Questionnaire

|                 |   |
|-----------------|---|
| End point title | Number of Participants who Seek Additional Care from a Dependent to Attend Appointment Assessed via Questionnaire |
|-----------------|---|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Yes, No, Not Applicable and Missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Yes                         | 16                         |  |  |  |
| No                          | 318                        |  |  |  |
| Not Applicable              | 39                         |  |  |  |
| Missing                     | 6                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants Taking Time Off from Work to Recover from any Injection Site Reaction Issue Assessed via Questionnaire

|                 |   |
|-----------------|---|
| End point title | Number of Participants Taking Time Off from Work to Recover from any Injection Site Reaction Issue Assessed via Questionnaire |
|-----------------|---|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The time off responses were categorized as No, On the day of receiving the treatment, One day after receiving the treatment, Two days after receiving the treatment, More than two days after receiving the treatment, Missing

response for Yes, Not Applicable and Missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Month 12             |           |

| End point values                                | Patient Study Participants |  |  |  |
|---|----------------------------|--|--|--|
| Subject group type                              | Reporting group            |  |  |  |
| Number of subjects analysed                     | 379                        |  |  |  |
| Units: Participants                             |                            |  |  |  |
| No  | 294                        |  |  |  |
| Yes, on the day of receiving the treatment      | 45                         |  |  |  |
| Yes, one day after receiving the treatment      | 9                          |  |  |  |
| Yes, two days after receiving the treatment     | 7                          |  |  |  |
| Yes, more than two days receiving the treatment | 5                          |  |  |  |
| Missing response for 'Yes'                      | 2                          |  |  |  |
| Not Applicable                                  | 16                         |  |  |  |
| Missing   | 5                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants with Appointment Reminders Received Assessed via Questionnaire

|                 |   |
|-----------------|---|
| End point title | Number of Participants with Appointment Reminders Received Assessed via Questionnaire |
|-----------------|---|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Phone calls, Text/SMS messages, Existing clinic app, E-mail, Reminder in the mail, Another reminder and I did not receive reminders.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Month 12             |           |



| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Phone calls                 | 80                         |  |  |  |
| Text/SMS messages           | 275                        |  |  |  |
| Existing clinic app         | 48                         |  |  |  |
| E-mail                      | 161                        |  |  |  |
| Reminder in the mail        | 21                         |  |  |  |
| Another reminder            | 3                          |  |  |  |
| I did not receive reminders | 14                         |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants with Things Tried to Reduce Soreness Following Injections Assessed via Questionnaire

|                 |   |
|-----------------|---|
| End point title | Number of Participants with Things Tried to Reduce Soreness Following Injections Assessed via Questionnaire |
|-----------------|---|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Take over-the-counter pain relievers, Use a hot compress, Use a cold compress, Avoid sitting for long periods of time, Light stretching and exercise, None of the above, Other and I don't get sore after my injections.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values                       | Patient Study Participants |  |  |  |
|--|----------------------------|--|--|--|
| Subject group type                     | Reporting group            |  |  |  |
| Number of subjects analysed            | 379                        |  |  |  |
| Units: Participants                    |                            |  |  |  |
| Take over-the-counter pain relievers   | 139                        |  |  |  |
| Use a hot compress                     | 20                         |  |  |  |
| Use a cold compress                    | 19                         |  |  |  |
| Avoid sitting for long periods of time | 87                         |  |  |  |
| Light stretching and exercise          | 71                         |  |  |  |
| None of the above                      | 61                         |  |  |  |
| Other                                  | 31                         |  |  |  |
| I don't get sore after my injections   | 72                         |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of PSPs with Facilitators for Acceptability Assessed via Semi Structured Interviews (SSIs)

|                 |   |
|-----------------|---|
| End point title | Number of PSPs with Facilitators for Acceptability Assessed via Semi Structured Interviews (SSIs) |
|-----------------|---|

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with facilitators for acceptability are presented.

Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to Month 12

| End point values                              | Patient Study Participants (PSPs) |  |  |  |
|---|-----------------------------------|--|--|--|
| Subject group type                            | Subject analysis set              |  |  |  |
| Number of subjects analysed                   | 110                               |  |  |  |
| Units: Participants                           |                                   |  |  |  |
| Feeling informed about injection              | 105                               |  |  |  |
| Overall positive experience                   | 100                               |  |  |  |
| Acceptable overall experience at clinic       | 82                                |  |  |  |
| In-person communication with HCP              | 76                                |  |  |  |
| Not worrying about taking medication          | 66                                |  |  |  |
| Experienced injector                          | 64                                |  |  |  |
| Acceptable clinic hours to receive injections | 51                                |  |  |  |
| injection experience met expectations         | 43                                |  |  |  |
| Patient travel facilitation                   | 33                                |  |  |  |
| injection experience better than expected     | 32                                |  |  |  |
| Staff responsiveness                          | 34                                |  |  |  |
| Number of visits                              | 30                                |  |  |  |
| Satisfaction with rescheduling process        | 29                                |  |  |  |
| Distance to clinic                            | 27                                |  |  |  |
| Not being reminded about HIV                  | 26                                |  |  |  |
| Acceptable time spent in clinic               | 25                                |  |  |  |
| Treatment adherence                           | 24                                |  |  |  |
| Gaining a sense of freedom                    | 24                                |  |  |  |

|  |    |  |  |  |
|--|----|--|--|--|
| Discreet treatment                         | 23 |  |  |  |
| Communication with staff                   | 22 |  |  |  |
| Reduced stigma due to injection            | 22 |  |  |  |
| Reduction in injection pain                | 20 |  |  |  |
| PP Medication for pain management          | 19 |  |  |  |
| Reduced stress due to injection            | 19 |  |  |  |
| HCP advice on pain management              | 18 |  |  |  |
| PP Activities to avoid for pain management | 16 |  |  |  |
| Website and/or internet                    | 15 |  |  |  |
| Characteristics of HCP communication       | 14 |  |  |  |
| Written materials and brochures            | 14 |  |  |  |
| Study materials                            | 14 |  |  |  |
| Time of informing                          | 13 |  |  |  |
| Collection, storage and preparation        | 12 |  |  |  |
| Fewer side effects                         | 12 |  |  |  |
| Time-saving approach                       | 12 |  |  |  |
| Activities for injection pain management   | 11 |  |  |  |
| Administration in other clinical setting   | 11 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of PSPs with Barriers for Acceptability Assessed via SSIs

|                 |  |
|-----------------|--|
| End point title | Number of PSPs with Barriers for Acceptability Assessed via SSIs |
|-----------------|--|

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with barriers for acceptability are presented.

Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to Month 12

| End point values                              | Patient Study Participants (PSPs) |  |  |  |
|---|-----------------------------------|--|--|--|
| Subject group type                            | Subject analysis set              |  |  |  |
| Number of subjects analysed                   | 110                               |  |  |  |
| Units: Participants                           |                                   |  |  |  |
| Injection side effects (Treatment Components) | 67                                |  |  |  |
| Injection side effects (Treatment Challenges) | 33                                |  |  |  |

|  |    |  |  |  |
|--|----|--|--|--|
| Injection experience worse than expected | 11 |  |  |  |
| Waiting time                             | 11 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of PSPs with Facilitators for Appropriateness Assessed via SSIs

|   |  |
|---|--|
| End point title   | Number of PSPs with Facilitators for Appropriateness Assessed via SSIs |
| End point description:<br>A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with Facilitators for appropriateness are presented. Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Up to Month 12  |  |

| End point values            | Patient Study Participants (PSPs) |  |  |  |
|-----------------------------|-----------------------------------|--|--|--|
| Subject group type          | Subject analysis set              |  |  |  |
| Number of subjects analysed | 110                               |  |  |  |
| Units: Participants         | 0                                 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of PSPs with Barriers for Appropriateness Assessed via SSIs

|   |  |
|---|--|
| End point title   | Number of PSPs with Barriers for Appropriateness Assessed via SSIs |
| End point description:<br>A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with barriers for appropriateness are presented. Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Up to Month 12  |  |

| End point values                                | Patient Study Participants (PSPs) |  |  |  |
|---|-----------------------------------|--|--|--|
| Subject group type                              | Subject analysis set              |  |  |  |
| Number of subjects analysed                     | 110                               |  |  |  |
| Units: Participants                             |                                   |  |  |  |
| Patient fearing or squeamish about injections   | 22                                |  |  |  |
| Patients not tolerating intramuscular injection | 12                                |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of PSPs with Facilitators for Feasibility Assessed via SSIs

|                 |  |
|-----------------|--|
| End point title | Number of PSPs with Facilitators for Feasibility Assessed via SSIs |
|-----------------|--|

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with facilitators for feasibility are presented. Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to Month 12

| End point values                               | Patient Study Participants (PSPs) |  |  |  |
|--|-----------------------------------|--|--|--|
| Subject group type                             | Subject analysis set              |  |  |  |
| Number of subjects analysed                    | 110                               |  |  |  |
| Units: Participants                            |                                   |  |  |  |
| Person to contact during CARISEL study         | 102                               |  |  |  |
| PP Calendar, Diary, Notes and/or Reminders     | 69                                |  |  |  |
| No missed appointment and rescheduling         | 65                                |  |  |  |
| Target date explained                          | 57                                |  |  |  |
| Easy to contact                                | 57                                |  |  |  |
| Contacting clinic staff during CARISEL study   | 52                                |  |  |  |
| Home administration by HCP                     | 41                                |  |  |  |
| No issues due to transportation and/or parking | 37                                |  |  |  |

|  |    |  |  |  |
|--|----|--|--|--|
| No challenges to receive injection               | 33 |  |  |  |
| Not contacting clinic staff during CARISEL study | 31 |  |  |  |
| No issues due to work                            | 28 |  |  |  |
| Clinic Reminder [all types]                      | 27 |  |  |  |
| Term of target date helpful                      | 25 |  |  |  |
| [PP] Setting reminders                           | 23 |  |  |  |
| Injection administration at GP office            | 22 |  |  |  |
| Injection administration at healthcare centers   | 19 |  |  |  |
| No issues to attend visits due to childcare      | 16 |  |  |  |
| [PP] Arrangements at work                        | 16 |  |  |  |
| Clinic reminder: Text and/or SMS                 | 14 |  |  |  |
| [PP] Appointment scheduling strategies           | 14 |  |  |  |
| No issues due to clinic hours                    | 13 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of PSPs with Barriers for Feasibility Assessed via SSIs

|                 |  |
|-----------------|--|
| End point title | Number of PSPs with Barriers for Feasibility Assessed via SSIs |
|-----------------|--|

End point description:

A semi-structured interview guide was developed to support the discussion surrounding experience with for the implementation of CAB+RPV LA injection treatment. The interview guide topics were informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework and Proctor Outcomes to facilitate discussions on the Acceptability, Appropriateness, Feasibility, and Sustainability from the PSPs' perspective. Results of number of PSPs with barriers for feasibility are presented.

Analysis was performed on patient study participants (PSPs) who participated in interviews. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Up to Month 12

| End point values                            | Patient Study Participants (PSPs) |  |  |  |
|---|-----------------------------------|--|--|--|
| Subject group type                          | Subject analysis set              |  |  |  |
| Number of subjects analysed                 | 110                               |  |  |  |
| Units: Participants                         |                                   |  |  |  |
| Target date not explained                   | 38                                |  |  |  |
| Missed appointment and/or rescheduling      | 23                                |  |  |  |
| Issues due to work                          | 21                                |  |  |  |
| Issues due to transportation and/or parking | 14                                |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in The Acceptability of Intervention Measure (AIM) Score in PSPs at Month 12

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in The Acceptability of Intervention Measure (AIM) Score in PSPs at Month 12 |
|-----------------|---|

End point description:

AIM assesses the acceptability of an intervention (i.e., perception among stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory). It is a four-item (1. The CAB+RPV injection treatment meets my approval for treating my HIV, 2. The CAB+RPV injection treatment is appealing to me, 3. I like the CAB+RPV injection treatment for my HIV, 4. I welcome the CAB+RPV injection treatment for my HIV) measure with a five-point rating scale, where 1=completely disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, and 5=completely agree. The mean score ranges from 1 to 5 with 1 indicating the least acceptability and 5 the most acceptability.

Analysis was performed on patient study participants (PSPs) who completed the surveys at the relevant timepoints. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Baseline (Month 1) and Month 12

|                                      |                            |  |  |  |
|--------------------------------------|----------------------------|--|--|--|
| <b>End point values</b>              | Patient Study Participants |  |  |  |
| Subject group type                   | Reporting group            |  |  |  |
| Number of subjects analysed          | 424                        |  |  |  |
| Units: Scores on a scale             |                            |  |  |  |
| arithmetic mean (standard deviation) |                            |  |  |  |
| Baseline (Month 1)                   | 4.55 (± 0.666)             |  |  |  |
| Month 12                             | 0.10 (± 0.834)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Feasibility of Intervention Measure (FIM) Score in PSPs at Month 12

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Feasibility of Intervention Measure (FIM) Score in PSPs at Month 12 |
|-----------------|---|

End point description:

The four-item (1. The CAB+RPV injection treatment seems implementable in my life 2. The CAB+RPV injection treatment every 2 months is possible for me to use 3. The CAB+RPV injection treatment every 2 months seems doable in my life 4. The CAB+RPV injection treatment every 2 months seems easy to use in my life). FIM assesses perceived intervention feasibility. The items are measured on a five-point rating scale, where 1=completely disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, and 5=completely agree. The mean score ranges from 1 to 5 with 1 indicating the least feasibility and 5 the most feasibility.

Analysis was performed on patient study participants (PSPs) who completed the surveys at the relevant timepoints. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Baseline (Month 1) and Month 12

| End point values                     | Patient Study Participants |  |  |  |
|--------------------------------------|----------------------------|--|--|--|
| Subject group type                   | Reporting group            |  |  |  |
| Number of subjects analysed          | 424                        |  |  |  |
| Units: Scores on a scale             |                            |  |  |  |
| arithmetic mean (standard deviation) |                            |  |  |  |
| Baseline (Month 1)                   | 4.51 ( $\pm$ 0.672)        |  |  |  |
| Month 12                             | 0.07 ( $\pm$ 0.857)        |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of PSP Receiving Injections within Target Window

|  |   |
|--|---|
| End point title  | Percentage of PSP Receiving Injections within Target Window |
| End point description:   |   |
| The target window for participants to receive injection was from Day -7 to Day 7.  |   |
| Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA. |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| Day -7 to Day 7  |   |

| End point values                  | Patient Study Participants (PSPs) |  |  |  |
|-----------------------------------|-----------------------------------|--|--|--|
| Subject group type                | Subject analysis set              |  |  |  |
| Number of subjects analysed       | 430                               |  |  |  |
| Units: Percentage of Participants | 93                                |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants with Confirmed Virologic Failure (CVF) Over Time

|  |   |
|--|---|
| End point title  | Number of Participants with Confirmed Virologic Failure (CVF) Over Time |
| End point description:   |   |
| CVF was defined as rebound as indicated by two consecutive plasma HIV-1 RNA levels $\geq 200$ c/ml. Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA. |   |
| End point type   | Secondary   |



End point timeframe:

Month 1, 2, 4, 8, 10 and 12

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 430                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Month 1                     | 0                          |  |  |  |
| Month 2                     | 0                          |  |  |  |
| Month 4                     | 0                          |  |  |  |
| Month 6                     | 0                          |  |  |  |
| Month 8                     | 0                          |  |  |  |
| Month 10                    | 1                          |  |  |  |
| Month 12                    | 0                          |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of PSPs with Adverse Events (AEs) And Serious AEs (SAEs)

|                 |   |
|-----------------|---|
| End point title | Number of PSPs with Adverse Events (AEs) And Serious AEs (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 intervention, whether or not considered related to the study intervention. An SAE is defined as any untoward medical occurrence that, at any dose may result in death or is life-threatening or requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity or is a congenital anomaly/birth defect or any other situation according to medical or scientific judgment or is associated with liver injury and impaired liver function.

Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA.

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

End point timeframe:

Up to 12 Months

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 430                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Any AEs                     | 420                        |  |  |  |
| Any SAEs                    | 15                         |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of PSPs Discontinuing Treatment Due to AEs

|                 |   |
|-----------------|---|
| End point title | Number of PSPs Discontinuing Treatment Due to AEs |
|-----------------|---|

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 intervention, whether or not considered related to the study intervention.

Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA.

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

End point timeframe:

Up to 12 Months

|                             |                            |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| End point values            | Patient Study Participants |  |  |  |
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 430                        |  |  |  |
| Units: Participants         | 2                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Implementation Leadership Scale (ILS) Score at Month 12

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Implementation Leadership Scale (ILS) Score at Month 12 |
|-----------------|---|

End point description:

The ILS is a 12-item (facilitate implementation, obstacles, clear department standards, knowledge, ability to answer questions, awareness of concept, recognition, support employee efforts to learn, support employee efforts to use intervention, persevere(s) through the ups and downs, carries on through the challenges and reaction to critical issues) measure that assesses SSP understanding of the degree to which leadership in their clinic/practice setting is proactive, knowledgeable, supportive, perseverant with regards to implementing the treatment in their settings. The items are measured on a five-point rating scale (1=very great extent,2=great extent,3=moderate extent,4=slight extent,5=not at all). The mean score ranges from 1 to 5. Higher the score means less understanding in leadership. Analysis was performed on FAS, which included all SSPs who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed

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

End point timeframe:

Baseline (Month 1) and Month 12

| End point values                     | Staff Study Participants |  |  |  |
|--------------------------------------|--------------------------|--|--|--|
| Subject group type                   | Subject analysis set     |  |  |  |
| Number of subjects analysed          | 69                       |  |  |  |
| Units: Scores on a scale             |                          |  |  |  |
| arithmetic mean (standard deviation) |                          |  |  |  |
| Baseline (Month 1)                   | 2.1 ( $\pm$ 0.85)        |  |  |  |
| Month 12                             | -0.1 ( $\pm$ 1.19)       |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Absolute Values of Implementation Climate Scale (ICS) Scores at Month 1 and Month 12

|   |  |
|---|--|
| End point title   | Absolute Values of Implementation Climate Scale (ICS) Scores at Month 1 and Month 12 |
| End point description:  |  |
| <p>The ICS is a 9 item (team’s main goals, importance of implementation, top priority, workshops, treatment training, training material, staff adaptability, flexibility, openness to new intervention) measure that assesses SSPs’ perceptions of their team (i.e., the people that they work with) while using the CAB LA + RPV LA injection treatment in their clinic/practice setting. The items were measured on a five-point rating scale (1 = very great extent, 2 = great extent, 3 = moderate extent, 4 = slight extent, and 5 = not at all). The mean score ranges from 1 to 5. Higher the score means less seriousness for implementation in staff.</p> <p>Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.</p> |  |
| End point type  | Secondary  |
| End point timeframe:  |  |
| Month 1 and Month 12  |  |

| End point values                     | Staff Study Participants – Enhanced Implementation Arm | Staff Study Participants – Standard Implementation Arm |  |  |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Subject analysis set                                   | Subject analysis set                                   |  |  |
| Number of subjects analysed          | 34   | 35   |  |  |
| Units: Scores on a scale             |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Month 1                              | 2.5 ( $\pm$ 0.65)                                      | 2.8 ( $\pm$ 0.80)                                      |  |  |
| Month 12                             | 2.7 ( $\pm$ 0.72)                                      | 2.6 ( $\pm$ 0.80)                                      |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants with Time it took them to Get to the Clinic where they receive HIV Treatment/Check-ups Assessed via Questionnaire

|                 |  |
|-----------------|--|
| End point title | Number of Participants with Time it took them to Get to the Clinic where they receive HIV Treatment/Check-ups Assessed via Questionnaire |
|-----------------|--|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The average time was categorized as Up to 15 minutes, 16-30 minutes, 31-45 minutes, 46-60 minutes, More than 60 minutes, and missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Up to 15 minutes            | 66                         |  |  |  |
| 16-30 minutes               | 138                        |  |  |  |
| 31-45 minutes               | 87                         |  |  |  |
| 46-60 minutes               | 44                         |  |  |  |
| More than 60 minutes        | 39                         |  |  |  |
| Missing                     | 5                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of participants that endorsed type of transportation used to attend appointments

|                 |   |
|-----------------|---|
| End point title | Number of participants that endorsed type of transportation used to attend appointments |
|-----------------|---|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The means of transport were categorized as Transportation service, Dropped-off, Private vehicle, Bicycle/scooter/skateboard/ walked, Public transport and Missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values                     | Patient Study Participants |  |  |  |
|--------------------------------------|----------------------------|--|--|--|
| Subject group type                   | Reporting group            |  |  |  |
| Number of subjects analysed          | 379                        |  |  |  |
| Units: Participants                  |                            |  |  |  |
| Taxi-Transportation service          | 13                         |  |  |  |
| Taxi- Public transport               | 10                         |  |  |  |
| Dropped-off                          | 12                         |  |  |  |
| Private vehicle                      | 164                        |  |  |  |
| Bicycle/ scooter/ skateboard/ walked | 49                         |  |  |  |
| Public transport                     | 138                        |  |  |  |
| Missing                              | 3                          |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants Rating Convenience of Clinic/Practice's Procedures for Scheduling Injections Assessed via Questionnaire

|                 |  |
|-----------------|--|
| End point title | Number of Participants Rating Convenience of Clinic/Practice's Procedures for Scheduling Injections Assessed via Questionnaire |
|-----------------|--|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The convenience responses were categorized as Extremely convenient, Very convenient, Somewhat convenient, A little convenient, Not at all convenient, Not applicable; I did not have to schedule and Missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Extremely convenient        | 175                        |  |  |  |
| Very convenient             | 154                        |  |  |  |
| Somewhat convenient         | 43                         |  |  |  |
| A little convenient         | 4                          |  |  |  |

|  |   |  |  |  |
|--|---|--|--|--|
| Not at all convenient                      | 0 |  |  |  |
| Not applicable; I did not have to schedule | 0 |  |  |  |
| Missing                                    | 3 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants Rating Convenience of Clinic/Practice's Procedures for Rescheduling Injections Assessed via Questionnaire

|                 |  |
|-----------------|--|
| End point title | Number of Participants Rating Convenience of Clinic/Practice's Procedures for Rescheduling Injections Assessed via Questionnaire |
|-----------------|--|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The convenience responses were categorized as Extremely convenient, Very convenient, Somewhat convenient, A little convenient, Not at all convenient, Not applicable; I did not have to reschedule and Missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values                           | Patient Study Participants |  |  |  |
|--|----------------------------|--|--|--|
| Subject group type                         | Reporting group            |  |  |  |
| Number of subjects analysed                | 379                        |  |  |  |
| Units: Participants                        |                            |  |  |  |
| Extremely convenient                       | 158                        |  |  |  |
| Very convenient                            | 153                        |  |  |  |
| Somewhat convenient                        | 25                         |  |  |  |
| A little convenient                        | 2                          |  |  |  |
| Not at all convenient                      | 0                          |  |  |  |
| Not applicable; I did not have to schedule | 39                         |  |  |  |
| Missing                                    | 2                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants Rating Feelings About Getting CAB+RPV Injection Treatment Assessed via Questionnaire

|                 |  |
|-----------------|--|
| End point title | Number of Participants Rating Feelings About Getting CAB+RPV |
|-----------------|--|

## End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Extremely positive, Very positive, Somewhat positive, A little positive, Not at all positive and Missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Extremely positive          | 234                        |  |  |  |
| Very positive               | 112                        |  |  |  |
| Somewhat positive           | 23                         |  |  |  |
| A little positive           | 4                          |  |  |  |
| Not at all positive         | 0                          |  |  |  |
| Missing                     | 6                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

**Secondary: Number of Participants that Rated Perceived Knowledge about CAB+RPV Injection Treatment Assessed via Questionnaire**

|                 |  |
|-----------------|--|
| End point title | Number of Participants that Rated Perceived Knowledge about CAB+RPV Injection Treatment Assessed via Questionnaire |
|-----------------|--|

## End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Extremely knowledgeable, Very knowledgeable, Somewhat knowledgeable, A little knowledgeable, Not at all knowledgeable and Missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Extremely knowledgeable     | 124                        |  |  |  |
| Very knowledgeable          | 188                        |  |  |  |
| Somewhat knowledgeable      | 57                         |  |  |  |
| A little knowledgeable      | 6                          |  |  |  |
| Not at all knowledgeable    | 0                          |  |  |  |
| Missing                     | 4                          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants who rated helpfulness of Appointment outside of Typical Work Times Assessed via Questionnaire

|                 |  |
|-----------------|--|
| End point title | Number of Participants who rated helpfulness of Appointment outside of Typical Work Times Assessed via Questionnaire |
|-----------------|--|

End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Extremely helpful, Very helpful, Somewhat helpful, A Little helpful, Not at all helpful and Missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Extremely helpful           | 135                        |  |  |  |
| Very helpful                | 123                        |  |  |  |
| Somewhat helpful            | 50                         |  |  |  |
| A Little helpful            | 38                         |  |  |  |
| Not at all helpful          | 28                         |  |  |  |
| Missing                     | 5                          |  |  |  |

## Statistical analyses



No statistical analyses for this end point

### Secondary: Number of Participants that Rated Agreement in Recommending the CAB+RPV Injections to Others Assessed via Questionnaire

|                 |   |
|-----------------|---|
| End point title | Number of Participants that Rated Agreement in Recommending the CAB+RPV Injections to Others Assessed via Questionnaire |
|-----------------|---|

#### End point description:

Study-specific questions were developed to gather data on the facilitators and barriers of the CAB LA + RPV LA injection treatment. The response options are different for each question. The responses were categorized as Completely agree, Agree, Neutral, Disagree, Completely disagree and Missing. Missing include participants who did not provide a response for the question.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values            | Patient Study Participants |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 379                        |  |  |  |
| Units: Participants         |                            |  |  |  |
| Completely agree            | 283                        |  |  |  |
| Agree                       | 75                         |  |  |  |
| Neutral                     | 15                         |  |  |  |
| Disagree                    | 1                          |  |  |  |
| Completely disagree         | 1                          |  |  |  |
| Missing                     | 4                          |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Intervention Appropriateness Measure (IAM) Score in PSPs at Month 12

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Intervention Appropriateness Measure (IAM) Score in PSPs at Month 12 |
|-----------------|--|

#### End point description:

IAM assesses the appropriateness of an intervention (i.e., the perceived fit, relevance, or compatibility of the innovation for a given practice setting, provider, or consumer; and the perceived fit of the innovation to address a particular issue or problem). It is a four-item (1.The CAB+RPV injection treatment is fitting for my life, 2.The CAB+RPV injection treatment is suitable for my life, 3.The CAB+RPV injection treatment is applicable to my life, 4.The CAB+RPV injection treatment is a good match for my life) measure with a 5-point rating scale, where 1=completely disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=completely agree. The mean score ranges from 1 to 5 with 1 indicating the least appropriateness and 5 the most appropriateness.

Analysis was performed on PSPs, which included all participants who successfully completed the survey at the relevant timepoints. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Baseline (Month 1) and Month 12

| End point values                     | Patient Study Participants |  |  |  |
|--------------------------------------|----------------------------|--|--|--|
| Subject group type                   | Reporting group            |  |  |  |
| Number of subjects analysed          | 423                        |  |  |  |
| Units: Scores on a scale             |                            |  |  |  |
| arithmetic mean (standard deviation) |                            |  |  |  |
| Baseline (Month 1)                   | 4.47 (± 0.762)             |  |  |  |
| Month 12                             | 0.13 (± 0.928)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Associated Person Clinical Sustainability Assessment Tool (APCSAT) Total Score at Month 12

|                 |  |
|-----------------|--|
| End point title | Associated Person Clinical Sustainability Assessment Tool (APCSAT) Total Score at Month 12 |
|-----------------|--|

End point description:

The APCSAT is a 35-item measure that assesses SSP impressions of the data in their clinic. Sustainability refers to the ability to maintain and expand the CAB LA + RPV LA injection treatment and its benefits over time. SSPs were asked to rate their clinic/practice along a range of specific factors that affect sustainability, including: 'Engages Staff & Leadership,' 'Engaging Stakeholders,' 'Monitoring and Evaluation,' 'Implementation & Training,' 'Outcomes & Effectiveness,' 'Workflow Integration,' and 'Organizational Readiness.' Five items were presented to SSPs in each domain. The total score for the APCSAT was assessed on a scale of 1=program has sustainability to no extent to 7=program has sustainability to the full extent. Analysis was performed on FAS, which included all staff study participants (SSPs) who completed at least one survey at any timepoint. Only those participants with data available at the specified time points were analyzed.

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

End point timeframe:

Month 12

| End point values            | Staff Study Participants (SSP) |  |  |  |
|-----------------------------|--------------------------------|--|--|--|
| Subject group type          | Subject analysis set           |  |  |  |
| Number of subjects analysed | 62                             |  |  |  |
| Units: Scores on a scale    |                                |  |  |  |
| number (not applicable)     | 5.32                           |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of PSPs With Plasma HIV-1 Ribonucleic Acid (RNA) Less Than (<)50 Copies Per Milliliter (C/ml)

|                 |  |
|-----------------|--|
| End point title | Percentage of PSPs With Plasma HIV-1 Ribonucleic Acid (RNA) Less Than (<)50 Copies Per Milliliter (C/ml) |
|-----------------|--|

End point description:

Plasma samples were collected from the participant at specific time points. Analysis was performed on Safety population, which included all enrolled participants who received at least one dose of CAB + RPV Oral or CAB LA + RPV LA.

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

End point timeframe:

Month 1, 2, 4, 8 and 12

| End point values                  | Patient Study Participants |  |  |  |
|-----------------------------------|----------------------------|--|--|--|
| Subject group type                | Reporting group            |  |  |  |
| Number of subjects analysed       | 430                        |  |  |  |
| Units: Percentage of Participants |                            |  |  |  |
| number (confidence interval 95%)  |                            |  |  |  |
| Month 1                           | 99 (97.0 to 99.5)          |  |  |  |
| Month 2                           | 96 (93.7 to 97.7)          |  |  |  |
| Month 4                           | 93 (90.5 to 95.4)          |  |  |  |
| Month 8                           | 86 (82.7 to 89.4)          |  |  |  |
| Month 12                          | 87 (83.2 to 89.8)          |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of PSP with Preference for Therapy Assessed via Preference Questionnaire

|                 |   |
|-----------------|---|
| End point title | Number of PSP with Preference for Therapy Assessed via Preference Questionnaire |
|-----------------|---|

End point description:

PSPs were asked to think about their experience of using the long-acting injectable medication versus the daily oral HIV medication, and to select their preferred treatment and all the reasons that support their preference. Results are categorized as: 'long-acting injectable HIV medication', 'daily oral HIV medication', 'no preference', Missing and Erroneous. Missing include participants who did not provide a response for the question. PSPs who completed this question incorrectly (i.e., checked reasons without a ticking a leading preference or checked more than one leading preference box) were included in Erroneous.

Analysis was performed on patient study participants (PSPs), which included all participants who successfully completed the survey at Month 12. Only those participants with data available at the specified time points were analyzed.

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

---

End point timeframe:

Up to 12 Months

---

| End point values                      | Patient Study Participants |  |  |  |
|---------------------------------------|----------------------------|--|--|--|
| Subject group type                    | Reporting group            |  |  |  |
| Number of subjects analysed           | 379                        |  |  |  |
| Units: Participants                   |                            |  |  |  |
| Daily oral HIV medication             | 2                          |  |  |  |
| Long-acting injectable HIV medication | 275                        |  |  |  |
| No preference                         | 0                          |  |  |  |
| Missing                               | 2                          |  |  |  |
| Erroneous                             | 100                        |  |  |  |

### Statistical analyses

---

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs), non-serious AEs and all-cause mortality were collected up to Month 12. Data collection is still on-going and additional results will be provided after study completion.

Adverse event reporting additional description:

Adverse events were reported for safety population which comprised of all participants enrolled and who received at least 1 dose of CAB LA+RPV LA. Staff Study Participants (SSP) did not receive oral lead-in medication or CAB+RPV LA injections. Adverse events for SSP were not collected because it was not required per study design.

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

### Dictionary used

|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | .23.1  |

### Reporting groups

|                       |                            |
|-----------------------|----------------------------|
| Reporting group title | Patient Study Participants |
|-----------------------|----------------------------|

Reporting group description:

Participants with HIV received one tablet of Cabotegravir (CAB) 30 milligrams (mg) + Rilpivirine (RPV) 25 mg once daily from Day 1 for 1 month during the oral lead-in phase (OLI). Participants received last dose of oral regimen followed by CAB long-acting injectable (LA) 600 mg + RPV LA 900 mg injections in Month 1, one month later (Month 2), and every 2 months (Q2M) thereafter via intramuscular (IM) route.

| Serious adverse events                            | Patient Study Participants |  |  |
|---|----------------------------|--|--|
| Total subjects affected by serious adverse events |                            |  |  |
| subjects affected / exposed                       | 15 / 430 (3.49%)           |  |  |
| number of deaths (all causes)                     | 0                          |  |  |
| number of deaths resulting from adverse events    |                            |  |  |
| Injury, poisoning and procedural complications    |                            |  |  |
| Subdural haemorrhage                              |                            |  |  |
| subjects affected / exposed                       | 1 / 430 (0.23%)            |  |  |
| occurrences causally related to treatment / all   | 0 / 1                      |  |  |
| deaths causally related to treatment / all        | 0 / 0                      |  |  |
| Subdural haematoma                                |                            |  |  |
| subjects affected / exposed                       | 1 / 430 (0.23%)            |  |  |
| occurrences causally related to treatment / all   | 0 / 1                      |  |  |
| deaths causally related to treatment / all        | 0 / 0                      |  |  |
| Clavicle fracture                                 |                            |  |  |
| subjects affected / exposed                       | 1 / 430 (0.23%)            |  |  |
| occurrences causally related to treatment / all   | 0 / 1                      |  |  |
| deaths causally related to treatment / all        | 0 / 0                      |  |  |

|  |                 |  |  |
|--|-----------------|--|--|
| Vascular disorders                                   |                 |  |  |
| Aortic dissection                                    |                 |  |  |
| subjects affected / exposed                          | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Nervous system disorders                             |                 |  |  |
| Orthostatic intolerance                              |                 |  |  |
| subjects affected / exposed                          | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| General disorders and administration site conditions |                 |  |  |
| Pyrexia  |                 |  |  |
| subjects affected / exposed                          | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Gastrointestinal disorders                           |                 |  |  |
| Appendicitis noninfective                            |                 |  |  |
| subjects affected / exposed                          | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Abdominal pain                                       |                 |  |  |
| subjects affected / exposed                          | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Reproductive system and breast disorders             |                 |  |  |
| Haemospermia   |                 |  |  |
| subjects affected / exposed                          | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Ovarian cyst   |                 |  |  |
| subjects affected / exposed                          | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Respiratory, thoracic and mediastinal disorders      |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| Pneumothorax                                    |                 |  |  |
| subjects affected / exposed                     | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Psychiatric disorders                           |                 |  |  |
| Major depression                                |                 |  |  |
| subjects affected / exposed                     | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Suicidal ideation                               |                 |  |  |
| subjects affected / exposed                     | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Renal and urinary disorders                     |                 |  |  |
| Haematuria                                      |                 |  |  |
| subjects affected / exposed                     | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Musculoskeletal and connective tissue disorders |                 |  |  |
| Intervertebral disc protrusion                  |                 |  |  |
| subjects affected / exposed                     | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Infections and infestations                     |                 |  |  |
| Appendicitis                                    |                 |  |  |
| subjects affected / exposed                     | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Yersinia infection                              |                 |  |  |
| subjects affected / exposed                     | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Peritonitis                                     |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| COVID-19  |                 |  |  |
| subjects affected / exposed                     | 1 / 430 (0.23%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |

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

| <b>Non-serious adverse events</b>                     | Patient Study Participants |  |  |
|---|----------------------------|--|--|
| Total subjects affected by non-serious adverse events |                            |  |  |
| subjects affected / exposed                           | 380 / 430 (88.37%)         |  |  |
| Nervous system disorders                              |                            |  |  |
| Headache  |                            |  |  |
| subjects affected / exposed                           | 36 / 430 (8.37%)           |  |  |
| occurrences (all)                                     | 45                         |  |  |
| General disorders and administration site conditions  |                            |  |  |
| Injection site pain                                   |                            |  |  |
| subjects affected / exposed                           | 342 / 430 (79.53%)         |  |  |
| occurrences (all)                                     | 1533                       |  |  |
| Injection site induration                             |                            |  |  |
| subjects affected / exposed                           | 43 / 430 (10.00%)          |  |  |
| occurrences (all)                                     | 74                         |  |  |
| Injection site discomfort                             |                            |  |  |
| subjects affected / exposed                           | 38 / 430 (8.84%)           |  |  |
| occurrences (all)                                     | 94                         |  |  |
| Pyrexia   |                            |  |  |
| subjects affected / exposed                           | 37 / 430 (8.60%)           |  |  |
| occurrences (all)                                     | 48                         |  |  |
| Injection site nodule                                 |                            |  |  |
| subjects affected / exposed                           | 32 / 430 (7.44%)           |  |  |
| occurrences (all)                                     | 57                         |  |  |
| Injection site swelling                               |                            |  |  |



|   |  |  |  |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Asthenia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>27 / 430 (6.28%)</p> <p>38</p> <p>25 / 430 (5.81%)</p> <p>29</p>  |  |  |
| <p>Gastrointestinal disorders</p> <p>Diarrhoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>27 / 430 (6.28%)</p> <p>32</p>                                    |  |  |
| <p>Musculoskeletal and connective tissue disorders</p> <p>Back pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>33 / 430 (7.67%)</p> <p>33</p>                                    |  |  |
| <p>Infections and infestations</p> <p>COVID-19</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasopharyngitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>68 / 430 (15.81%)</p> <p>72</p> <p>25 / 430 (5.81%)</p> <p>25</p> |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment   |
|------------------|---|
| 02 December 2020 | Changes were made to correct discrepancies in the document and to update the statistical section based on Ethics Committee requirement. |
| 01 July 2021     | To allow participants who become pregnant while in the study to remain in the study and not be withdrawn due to pregnancy.              |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported