



PREFER-LA:

Improved adherence and viral control in a real-world study of people with HIV in the United States with adherence challenges on oral antiretroviral therapy (ART) switching to cabotegravir + rilpivirine long-acting (CAB+RPV LA)

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Disclosures

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Disclosures:

William R. Short reports consulting for ViiV and Gilead, research grants paid to institution; Rebecca Glassman reports Gilead Speaker Series; Christina Harbison reports ViiV Speaker Bureau, consultant for Thera Technologies, research grants paid to institution; Mitchell Whitehead reports no disclosures.

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Ann Linskey, Jimena Patarroyo, Edgar T. Overton, Cindy Garris, and Andrew P. Brogan are employees of ViiV Healthcare and may own stock in GSK. Deanna Merrill was an employee of ViiV Healthcare and may own stock in GSK.

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Study Rationale

There is limited real-world US evidence on the use of CAB+RPV LA in individuals with documented adherence barriers

Background

-  Achieving and sustaining viral suppression in people with HIV requires consistent and sustained adherence to antiretroviral therapy (ART)^{1,2}
-  Missed doses can lead to viral rebound, drug resistance, and worse clinical outcomes^{1,2}
-  Despite potent and simplified single-tablet regimens, many people with HIV struggle with adherence due to forgetfulness, lifestyle constraints, pill fatigue, stigma, and access barriers¹⁻³
-  CAB+RPV LA, given monthly or every two months, may overcome these barriers^{4,5}
-  In the LATITUDE randomized controlled trial, CAB+RPV LA showed superior efficacy versus oral ART in participants with adherence challenges^{6,7}

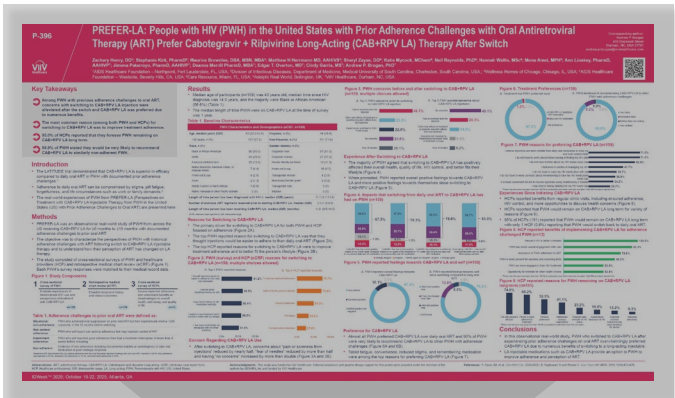
CAB+RPV LA, Cabotegravir and rilpivirine long acting.

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PREFER-LA Study Objectives

Participant Perspectives

- Detailed in companion poster
- Poster results highlighted motivations, perceived needs, and expectations



See Poster P-396
for more information



Clinical and Adherence Outcomes

- Types of adherence challenges prior to switching
- Viral load outcomes
- Frequency of missed or delayed injections

Study Design

Observational, cross-sectional US study of people with HIV on CAB+RPV LA for 6-18 months

Study Population:

Adults ≥ 18 years with HIV-1 who had been on CAB + RPV LA for 6-18 months

Documented adherence challenges on prior oral therapy as identified by their healthcare professional (HCP)

Data Sources:



Individual Survey n=159

Cross-sectional survey: Assessed experiences with oral therapy and perceptions of LA therapy in individuals with prior adherence challenges



eCRF n=159

Corresponding retrospective medical chart review: Assessed treatment history and clinical outcomes of participants on CAB+RPV LA; adherence data abstracted by HCP



HCP survey n=13

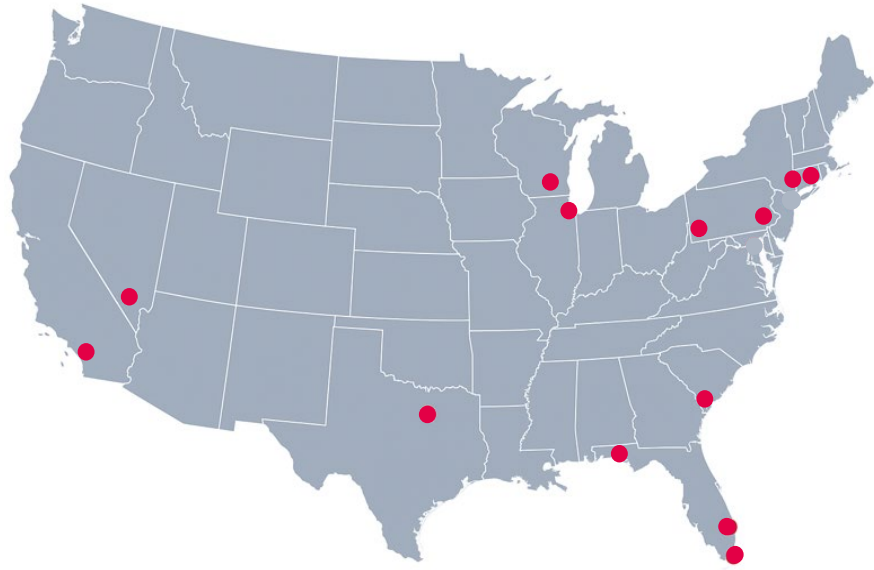
Cross-sectional HCP survey: Assessed participant adherence and benefits/disadvantages to overall health, well-being, and quality of life

*Prescribers, injectors, nurses, pharmacists, and/or those directly involved with people with HIV care.
 CAB+RPV LA, Cabotegravir and rilpivirine long acting; eCRF, Electronic case report form; HCP, Healthcare professional; LA, Long acting; US, United States.



Characteristics and Demographics (n=159)

Geographic Distribution of Study Sites (n=13 sites)



Age, median years (IQR)		Ethnicity, n (%)*	
< 50 years (%)		Hispanic, n (%)	44 (28)
≥ 50 years (%)		Non-Hispanic, n (%)	111 (70)
Race, n (%)*		Gender Identity, n (%)**	
Black or African American	90 (57)	Cisgender man	97 (61)
White	46 (29)	Cisgender woman	27 (17)
A race(s) not listed here	20 (13)	Gender identity not listed	18 (11)
Native American, American Indian, or Alaskan Native	7 (4)	Prefer not to say	10 (6)
Prefer not to say	4 (3)	Transgender woman	4 (3)
Asian	2 (1)	Non-binary/Gender queer	3 (2)
Middle Eastern or North African	1 (1)	Transgender man	0 (0)
Native Hawaiian or other Pacific Islander	0 (0)	Intersex	0 (0)
Dosing frequency of CAB+RPV LA, n (%)			
Every two months injection		151 (95)	
Length of time person has been diagnosed with HIV-1, median (IQR) (years)		12 (6-21)	
Number of previous ART regimens received prior to starting CAB+RPV LA, median (IQR)		2 (1-4)	
Prior non-nucleoside reverse transcriptase inhibitor (NNRTI) exposure, n (%)		30 (28)	
Prior integrase inhibitor (INI) exposure, n (%)		50 (46)	
Length of time person has been receiving CAB+RPV LA, median (IQR) (months)		12 (9-15)	

*From individual survey (n=159); Participants could select more than one option.
 **Gender identity was self-reported by participants via survey; sex assigned at birth was abstracted from the eCRF.
 No resistance data were available at time of CAB+RPV LA initiation for 38% of PWH
 ART, Antiretroviral therapy; CAB+RPV-LA, Cabotegravir and rilpivirine long acting; eCRF, Electronic case report form; INI, Integrase inhibitor; IQR, Interquartile range; NNRTI, Non-nucleoside reverse transcriptase inhibitor.





Prior Oral ART Adherence Challenge Categories, n (%)*

29 (18%)	Situational non-adherence	Individuals who achieved viral suppression on prior oral ART but then experienced viremia >200 copies/mL in the 12 months before switching
96 (60%)	Sub-optimal adherence	Individuals who self-report sub-optimal adherence but may maintain control of HIV
6 (4%)	Intermittent adherence	Individuals who self-reported good adherence then had a treatment interruption of more than 4 weeks before resuming
42 (26%)	Non-adherence	Evidence of non-adherence including documented inability or unwillingness to take oral medication or poor virologic response

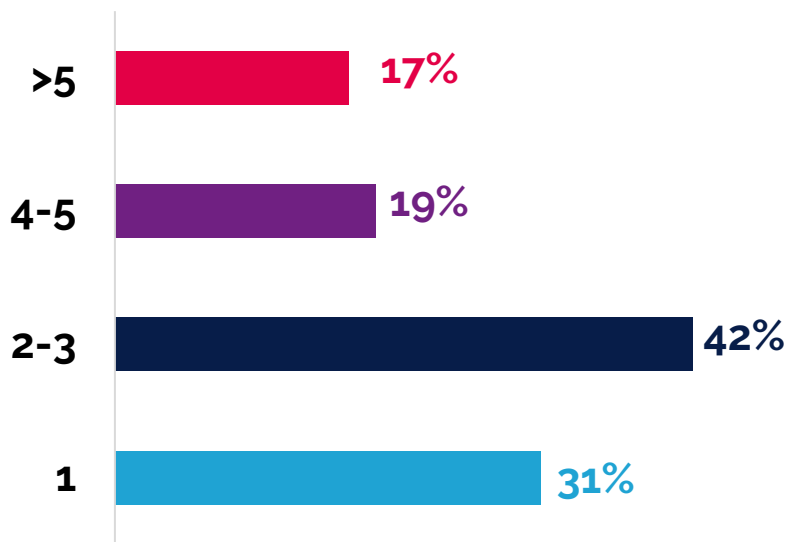
*HCP reported type of sub-optimal adherence patients experienced when receiving their previous oral ART in the 12 months prior to CAB+RPV LA initiation; multiple selections allowed, n = 12 selected multiple options.
 ART: Antiretroviral therapy.

ART History Prior to CAB+RPV LA

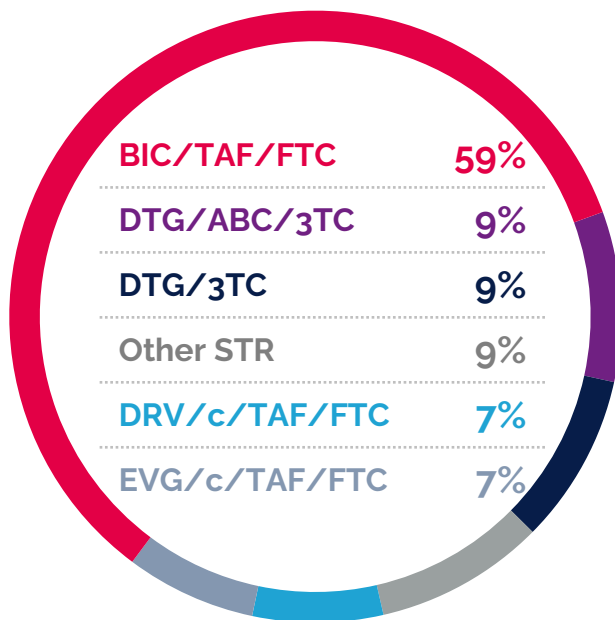
 Nearly **70%** of participants had received two or more prior regimens before switching to CAB+RPV LA

 **91%** switched from a single-tablet oral regimen, most commonly BIC/TAF/FTC

Number of ART regimens received prior to CAB+RPV LA initiation (n = 159)



Top 5 single tablet regimens immediately prior to switching to CAB+RPV LA (n = 145)



ART, Antiretroviral therapy; CAB+RPV LA, Cabotegravir and rilpivirine long acting; BIC/TAF/FTC, Bictegravir/tenofovir alafenamide/emtricitabine; EVG/c/TAF/FTC, Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine; DTG/ABC/3TC, Dolutegravir/abacavir/lamivudine; DTG/3TC, Dolutegravir/lamivudine; DRV/c/TAF/FTC, Darunavir/cobicistat/tenofovir alafenamide/emtricitabine; STR, Single-tablet regimen.



Participants reported a diverse range of adherence challenges with previous oral ART*



84%

Difficulty remembering daily doses



67%

Tired of taking a pill every day



50%

Felt the need to hide daily oral HIV medication from others



35%

Inconvenient routine for daily oral HIV medication



31%

Worried about running out of medication



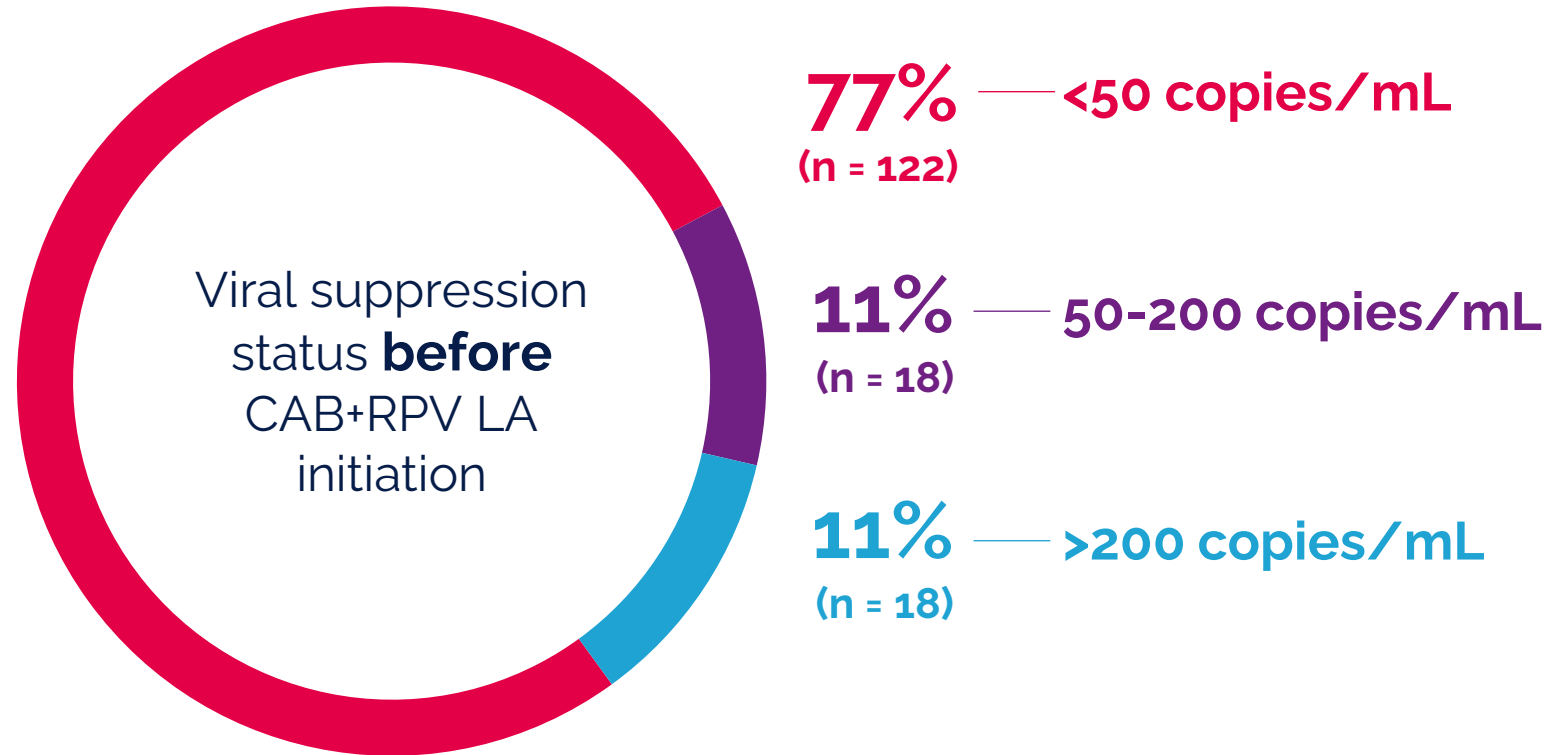
27%

Daily oral HIV medication had a negative effect on mood

*Values represent % of Individual survey respondents selecting each challenge; multiple responses allowed.
ART, Antiretroviral therapy.



89% had viral load ≤ 200 copies/mL before CAB+RPV LA initiation*



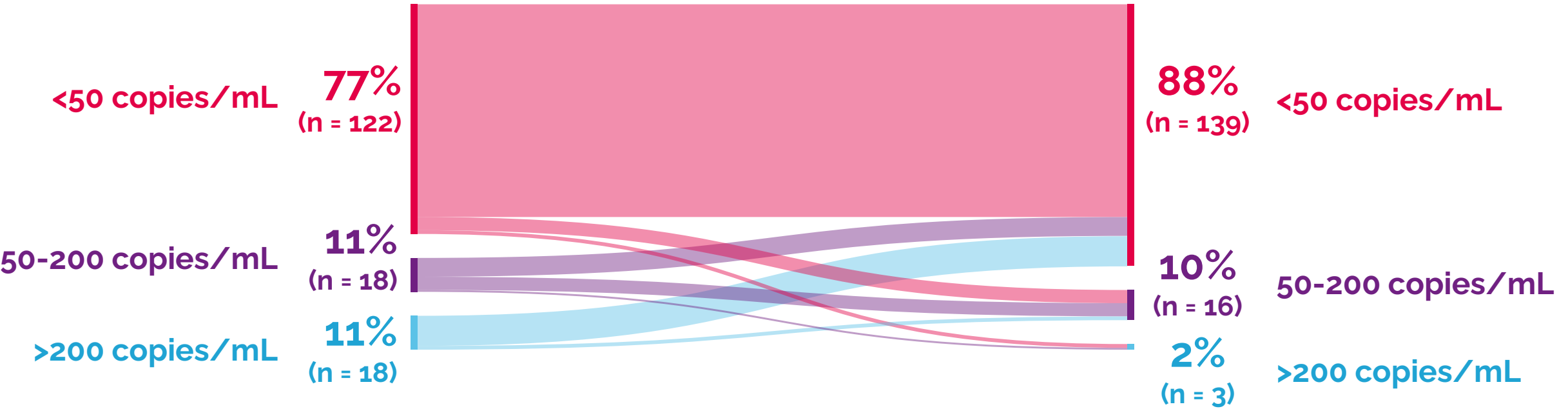
*Viral suppression data was missing for 1 person;



After switch to CAB+RPV LA, 98% achieved or maintained viral load ≤ 200 copies/mL*

Viral suppression status
BEFORE CAB+RPV LA initiation

Viral suppression status
AFTER CAB+RPV LA initiation



89% had viral load ≤ 200 copies/mL before CAB+RPV LA initiation

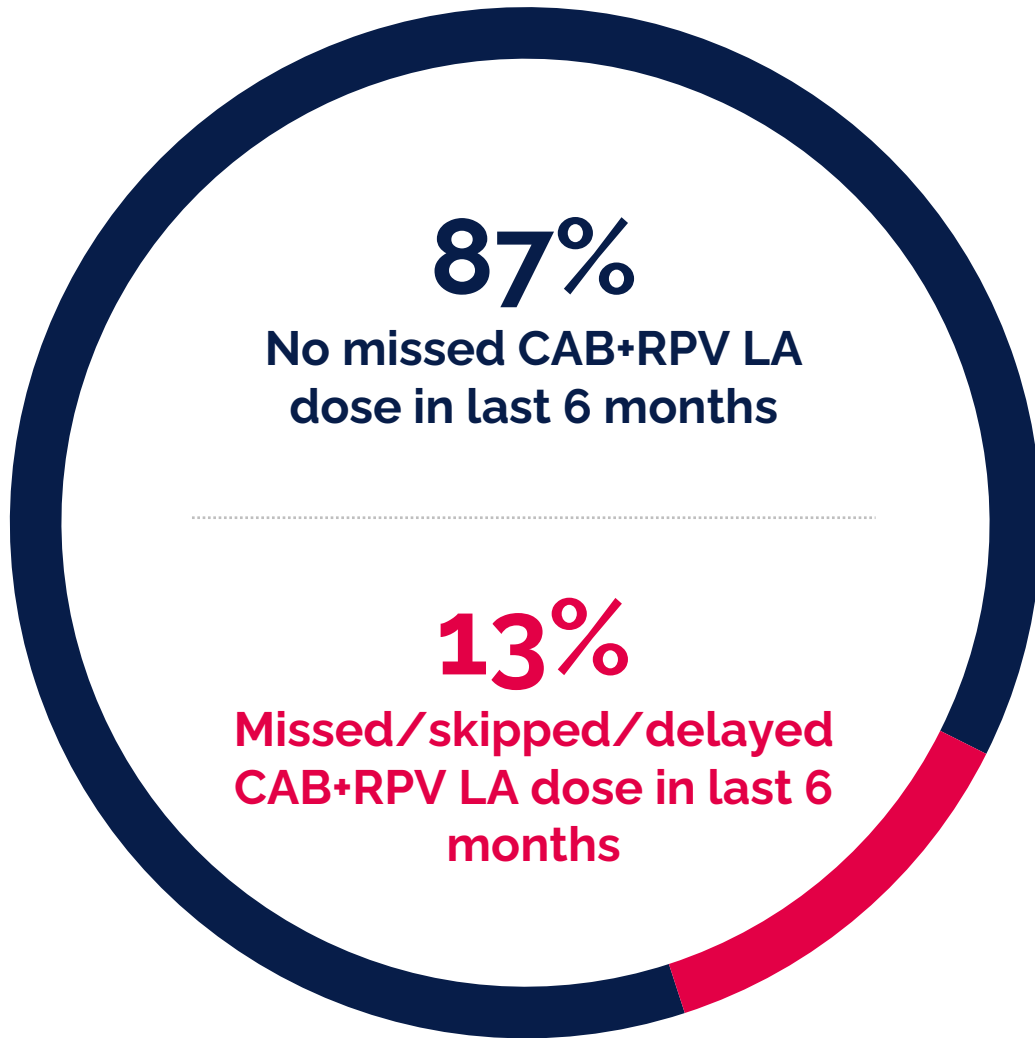
98% achieved or maintained viral load ≤ 200 copies/mL after CAB+RPV LA initiation

*Viral suppression data was missing for 1 person; Median time on CAB+RPV LA by viral suppression status at CAB+RPV LA initiation was: suppressed (n=122) 364 days, controlled (n=18) 363 days, not controlled (n = 18) 368 days.

ART, Antiretroviral therapy; CAB+RPV LA, Cabotegravir and rilpivirine long acting; HCP, Healthcare provider.



Most participants had on-time CAB+RPV LA injections



Reasons for No Missed Doses

- CAB+RPV LA fits well into daily life and routines (integration into schedules, less daily burden)
- Convenience of clinic visits and in-person support
- Preference for appointment reminders to help stay on track

Reasons for Missed/Skipped/Delayed Doses

- Forgetting appointments (38%)
- Appointment did not fit with work/social/travel plans (31%)
- Insurance coverage or out-of-pocket cost issues (25%)
- Transport issues (25%)

Limitations



Individual Survey

Minimal administrative burden (≤30 min online format)

Self-reported data subject to recall bias



eCRF

Limited by medical record completeness / accuracy

May not capture participants with undocumented or unreported sub-optimal adherence



Study Population

Site feasibility may introduce selection bias

Adherence classification may reflect physician judgement

Conclusions



CAB+RPV LA was associated with high rates of viral suppression in individuals with prior adherence challenges to oral ART



Results align with clinic trial and real-world data, supporting long-acting injectables for adherence-challenged populations



Ongoing monitoring needed to confirm durability and persistence

Looking Ahead

CAB+RPV LA is being examined in the ongoing CROWN phase 3b clinical trial of people with HIV with detectable viremia (NCT06694805)

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As the only pharmaceutical company solely focused on HIV, ViiV Healthcare's mission to leave no person living with HIV behind is resolute. We have an unwavering commitment to developing innovative medicines for the treatment and prevention of HIV in impacted communities. Clinical trial enrollment and real-world evidence generation that is representative of the populations most impacted by HIV is essential to delivering on our mission.

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