Real-World Use of *Apretude* for Pre-Exposure Prophylaxis

Summary

- A growing body of real-world evidence (RWE) have been reported on the use of *Apretude* (long-acting cabotegravir [CAB LA]) for pre-exposure prophylaxis (PrEP).
- In general, low rates of incident HIV infection with use of CAB LA for PrEP have been reported in RWE studies, and are consistent with results from the phase 3 HPTN 083 and 084 clinical trials.[1-19]
- Reported rates of PrEP continuation and adherence to injections after CAB LA initiation were consistent across the available data.[1-18,20]
- While safety data is limited, results are consistent with Phase 3 clinical trials; the most common adverse events reported were injection site reactions.[1-18]
- Important Safety Information and Boxed Warning can be found in the Prescribing Information and can also be accessed from Our HIV Medicines.

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HIV testing in RWE studies may not be consistently done according to the label, which may lead to under representation of HIV seroconversions reported. Potential overlap between patient cohorts presented below cannot be ruled out.

OPERA

OPERA is a prospectively captured cohort of routine clinical data from electronic health records in the US (101 clinics, 23 states/territories).[1,2] Data were retrospectively reviewed to assess CAB LA PrEP usage/adherence over 3 years and estimate the real-world incidence of HIV acquisition during CAB LA PrEP use. Additionally, HIV testing and acquisition was compared to oral PrEP users within this cohort. For this comparison, PrEP episodes were defined as continuous use of either CAB LA or oral PrEP; all episodes during the study period were included.

Participants were ≥ 18 years of age at the time of PrEP initiation and either received ≥ 1 CAB LA injection or a new oral PrEP regimen between December 21, 2021 and June 30, 2024; follow up was conducted through June 30, 2025.[1,2]

Overall, 1664 CAB LA PrEP users (1912 episodes) and 38,329 oral PrEP users (39,193 episodes) were included in the analysis; 157 users switched from CAB LA to oral PrEP and 825 switched from oral to CAB LA during the study period.[2] Baseline characteristics are described in Table 1.

Table 1. Characteristics at Start of PrEP Episode[2]

	CAB LA PrEP Episodes (N = 1912)	Oral PrEP Episodes (N = 39,193)
Age, median (IQR), years	33 (27, 41)	31 (26, 38)
Women, %	12	9
Black race, %	28	24
Hispanic ethnicity, %	28	34
Syphilis (past 3 months), %	14	12
Gonorrhea (past 3 months), %	9	12
Chlamydia (past 3 months), %	8	9

During the first 12 months since PrEP start, 1 HIV acquisition was identified during CAB LA PrEP episodes (incidence ratio [IR] per 1,000 person-years [95% CI]: 0.9 [0.1-6.5]) and 180 (IR [95% CI]: 4.9 [4.3-5.7]) during oral PrEP episodes (< 1% for both).[2] The HIV acquisition occurred 3 months after CAB LA PrEP start; the median (IQR) time to diagnosis from start of oral PrEP episode was 7 (4, 10) months. When compared with oral PrEP, the incidence rate ratio of HIV acquisition within the first 12 months of PrEP episode for CAB LA was 5.37 (95% CI 0.75-38.32).

Median (IQR) PrEP coverage within the first 12 months of PrEP episode start was 93% (81, 100) for CAB LA (median [IQR] follow-up: 11 [4, 12] months) and 58% (25, 94) for oral PrEP (median [IQR] follow-up: 12 (12, 12) months).[2]

HIV testing was performed more frequently during CAB LA episodes compared with oral PrEP episodes (IR per person-years [95% CI]: 6.51 (6.38-6.65) and 2.90 (2.89-2.92), respectively.[2]

In the 3-year analysis, 1748 individuals received at least 1 CAB LA PrEP injection; 1547 completed initiation and 1411 received at least 1 maintenance injection. HIV acquisition during the first continuous CAB LA PrEP use occurred in 2 participants over 1906.2 person-years of follow-up (IR [95% CI] 0.10 per 100 person-years [0.03-0.42]).[1]

Case 1 was diagnosed with HIV 3 months after CAB LA PrEP initiation; timing of seroconversion would not be determined as the last negative test was performed prior to oral PrEP start and patients subsequently transferred care.[1] Case 2 was diagnosed 21 months after CAB LA PrEP initiation; genotype results performed around the time of HIV diagnosis showed non-nucleoside reverse transcriptase and protease inhibitor mutations; the individual was started on darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide (DRV/c/FTC/TAF), and subsequently changed to bictegravir/ emtricitabine/ tenofovir alafenamide (BIC/FTC/TAF) with. Most recent HIV-1 RNA of 30 copies/mL.

Two additional HIV acquisitions were observed 4 and 6 months after CAB LA discontinuation, respectively.[1]

Among complete initiators, median (IQR) time from first injection to censoring was 13 (9, 19) months.[1] During the follow-up period, 32% discontinued CAB LA; 138 (28%) resumed CAB LA injections after discontinuation.

Adherence was assessed among complete initiators with at least 1 maintenance injection (n = 1411). Overall, 59% had all on-time injection and 41% had any late injections (828 total late injections).[1] Among those with delays, 85% did not require reinitiation.

Safety data was not reported from the OPERA cohort.[1,2]

TRIO HEALTH COHORT[3]

A retrospective analysis of electronic medical records data from the Trio Health HIV Network in the US was conducted to assess CAB LA PrEP use, HIV testing patterns, persistence, adherence, and HIV acquisition. Adult participants who received at least 1 CAB LA injection between December 2021 and February 2025 were included.

Overall, 1696 individuals received at least 1 CAB LA injection; median (IQR) age was 34 (28, 43), 83% were male, 52% were White, 28% were Black or African American, and 23% were Hispanic or Latino. Most (70%) had a history of prior oral PrEP use.

After a median (IQR) follow up of 12 (6, 20) months, 89% (n = 1509) completed initiation injections and 76% (n = 1296) received at least 3 injections; 64% of complete initiators remained on CAB LA at the end of follow-up. Thirty-six percent discontinued CAB LA; 14% reinitiated within 6 months.

Three HIV diagnoses were identified during the study period (0.2%); 2 were incident cases and 1 potential prevalent case. One individual had 7 on-time injections, with HIV diagnosis at 7th injection. The second individual had 10 injections, with missed second dose (did not complete initiation but continued CAB LA); HIV diagnosis occurred after the 10th injection. The third individual had 2 injections; HIV antibody was nonreactive at first injection, with no record of HIV RNA screening; HIV RNA was detected at second injection (antibody screening not performed. All individuals were treated with DRV/c/FTC/TAF; 2 achieved virologic suppression during 2 months of follow-up. No resistance mutations were detected in the first 2 individuals; testing was not performed for the third individual.

Of those that received their second injection (n = 1509), 83% were on-time, 12% had at least 1 delayed injection, and 5% had at least 1 incomplete initiation. Among participants who received at least 3 injections (n = 1296), 61% had all continuation injections administered on-time, 32% had at least 1 delayed injection, and 7% with at least 1 missed injection.

At initiation, 65% had both antigen/antibody and RNA tests and 78% at either test. During follow-up injections, 21% had both tests and 45% had at least 1 test.

Safety data was not reported in this analysis.

IMPREP CAB BRAZIL

An implementation study of CAB LA for PrEP was conducted among young men who have sex with men (MSM), non-binary, and transgender people in Brazil.[4] Participants were at 18–30 years old, PrEP naïve, and were seeking PrEP or HIV testing in 6 public services centers across 6 different cities in Brazil. The choice of either oral PrEP or CAB LA were offered. In all cohorts, 3rd generation rapid HIV tests were utilized and HIV RNA testing was done prior to loading dose injections in the CAB LA cohort. A comparison cohort consisting of participants who were PrEP naïve and initiated oral PrEP during the study period through the public health system was included in the analysis.

PrEP coverage was defined as the proportion of days covered by oral PrEP (possessing ≥ 4 pills/week) or CAB LA (6 weeks after first injection, 10 weeks after subsequent injections) during follow up.[4] Participants were enrolled from October 2023 through September 2024, and data was collected through January 15, 2025.

Overall 1447 participants were enrolled; 83% (n = 1200) chose CAB LA and 17% (n = 247) chose oral PrEP.[4] The oral PrEP comparison cohort included 2411 participants.

In all three groups (CAB LA, oral PrEP choice, oral PrEP comparison), most participants were 25—30 years old (62%, 58%, and 62%, respectively), cisgender MSM (91%, 93%, and 90%, respectively), and were Black/Pardo or Mixed/Other (61%, 58%, and 52%, respectively).[4] Median (IQR) follow-up was 7 (4.9, 10.1) months in the CAB LA cohort, 4.9 (1.1, 8.3) months in the oral PrEP choice cohort, and 3.7 (0.9, 7.7) months in the oral PrEP comparison cohort.

In the initial analysis, no seroconversion were reported in the CAB LA group (745.2 person-years), compared with 1 in the oral PrEP choice group (100.3 person-years; incidence rate: 1.0 (95% CI 0.0 to 5.6) per 100 person-years) and 9 in the oral PrEP comparison group (607.1 person-years; incidence rate: 1.5 (95% CI 0.7 to 2.8) per 100 person-years).[4]

A subsequent analysis reported 4 HIV-1 acquisitions (November 2023 through September 2024) in participants on CAB LA.[19] All were men who have sex with men (age range 19-25). One acquisition was retrospectively detected at CAB initiation, with antibody test reactive at Month 9. A second participant had HIV-1 RNA detected at Month 13 (HIV-1 RNA 490 and 655 on 2 separate assays) with positive serology detected at this time. The third participant had an HIV-1 RNA detected at 1.9 at Month 11 with positive serology and HIV-1 RNA of 19,500 at Month 13. The fourth had HIV-1 RNA of 343 detected at Month 13 with positive serology and no subsequent injections administered. Major INSTI mutations were detected in 1 participant (Q148R and N155H).

PrEP coverage was significantly higher in the CAB LA group compared with the oral PrEP choice and oral PrEP comparison cohorts (95% vs 58% and 48%, respectively; $P < 0.001$ for both comparisons).[4]

In the CAB LA cohort, 94% of injections were on-time (defined as performed ±7 days from the target date).[4] Six percent (n = 71) of participants were lost to follow-up after receiving at least one injection and 3% (n = 40) required re-initiation dosing. Four percent (n = 44) switched from CAB LA to oral PrEP due to side effects (n = 28), travel or relocation (n = 8), and preferring not to continue CAB LA (n = 8). Nine percent (n = 21) switched from oral PrEP to CAB LA due to preferring not to take pills (n = 17), changed decision (n = 2), and side effects (n = 2).

ITALIAN REAL-WORLD COHORTS

Italian PrIDE Cohort[5]

The Italian PrIDE cohort, which enrolled PrEP users from December 2024 through August 15, 2025, evaluated PrEP coverage and discontinuation among those on CAB LA compared with oral PrEP.

Overall, 2852 indivdiuals were included (CAB LA, n = 449; oral PrEP, n = 2403). Median (IQR) age aws 38 (32, 46), 99% were Male, and 63% were PrEP naïve. Median (IQR) follow-up was 123 (52, 164) days for oral PrEP and 179 (154, 197) for CAB LA.

No seroconversions were observed in this cohort.

The 1-year probability of discontinuation was 9% (95% CI 7.8-10.1) for oral PrEP (IR 30 per 100 person-years [95% CI 25-33]) and 2% (95% CI 0.2-3.8) for CAB LA (IR 3 [95% CI 1-6]; $P < 0.0001$).

The median (IQR) proportion of days covered (PDC) was higher with CAB LA compared with oral PrEP (100 [100, 100] vs 95 [75, 100], respective; $P < 0.001$).

Overall, 96% of injections were administered on-time (not defined; percentages of delayed and missed injections were not reported). Six CAB LA interruptions were reported due to: allergic reaction (n = 1), reduction in risk perception (n = 2), side effects (n = 2), and logistic issues (n = 1); 5 of these individuals switched to FTC/TDF.

Moschese D, et al.[6]

A multicenter, prospective, observational cohort study was conducted in two Italian centers in Milan and Rome from December 2024 through September 2025 in participants who were prescribed CAB LA for PrEP. Overall, 377 individuals were included who had barriers to oral PrEP or part of key populations at higher risk of HIV acquisition (due to limited number of vials).

Participants were mostly male (96%) and median (IQR) age was 38 (31, 46) years. Median (IQR) follow-up time was 28 (21, 29) weeks. Probability of retention at 28 weeks was 92%. No breakthrough HIV infections were reported. Ninety-three percent of injections were administered on time.

Eight percent (n = 31/377) discontinued CAB LA; 3% (n = 11) due to drug-related reasons, 4% (n = 16) were unrelated to treatment, and 1% (n = 4) were lost to follow-up. Reasons for treatment-related discontinuations included: pain, fatigue, arthromyalgias, hypersensitivity, gastrointestinal intolerance, weight or libido changes, preference for oral PrEP, and patient's choice.

The most common adverse events reported were pain (75% at first dose, 58% at second dose) and nodules (22% at first dose, 14% at second dose).

PREPFACTS

PrEPFACTS aimed to describe PrEP switching patterns, HIV testing patterns, and CAB LA effectiveness based on data from a US claims database from December 1, 2020 to September 30, 2023.[7] Individuals ≥ 12 years of age were included if they received at least 1 CAB LA injection after December 20, 2021, with the first claim for CAB LA defined as the index date. Continuous insurance eligibility was required during the baseline (≥ 12 months before index date) and follow-up (≥ 6 months after index date) periods. Individuals were excluded if they had any HIV-1 diagnosis during baseline or on the index date or had ≥ 60 days of non-PrEP ART for HIV during the baseline period.

During follow-up, PrEP discontinuation was defined as a gap of ≥ 60 day since last available days of supply.[7] CAB LA discontinuation was defined as a gap of ≥ 91 days between 2 consecutive CAB LA injection during the initiation phase or ≥ 121 days during the continuation phase. Evidence of HIV was defined as an HIV diagnosis code and having claims of oral ART for ≥ 60 days. Individuals were followed through end of continuous enrollment, death, or end of the follow-up period.

Adherence and utilization was also reported; the proportion of days covered (PDC [number of days during which an individual is taking CAB LA/number of days from index to discontinuation]) was used which ranged from 0 to 1 from the index to earliest of therapy discontinuation or end of follow-up.[20] Timing of injection administration was assessed both if within the target dosing window and within the time frame in which dosing reinitiation is not required.

Overall, 1202 individuals were included. Mean age (SD) was 37 (12) years, 83% were male, 31% White, and 22% Black or African American, and 18% were Hispanic or Latin American.[7] Most had prior PrEP experience (73%), 41% of which switched from oral PrEP to CAB LA. Median (IQR) follow-up was 325 (242, 423) days.

By the end of the follow-up period, 54% (n = 649/1202) continued on CAB LA.[7] Of the individuals who discontinued CAB LA (n = 553/1202 [46%]), 102 reinitiated CAB LA and 135 switched to oral PrEP (90 individuals continued on oral PrEP by the end of follow-up and 45 discontinued oral PrEP).

HIV testing was reported for 60% (n = 3564/5941) of all injections (65% [n = 1440/2226] for initiation injections and 57% [n = 2124/3715] for continuation injections).[7]

Three individuals (0.2%) had evidence of HIV after the index date.[7] Individual 1 initiated CAB LA 5 days prior to first evidence of HIV-1, and had a negative HIV Ag/Ab test on Day 0. The other two individuals discontinued CAB LA after 1 injection. Individual 2 had a negative HIV antibody test 14 days prior to CAB LA initiation and had first evidence of HIV-1 on Day 111. Individual 3 had a negative HIV antigen/antibody test 2 days prior to CAB LA initiation and first evidence of HIV-1 on Day 135. All three patients were switched to integrase strand transfer inhibitor (INSTI)-based regimens following HIV-1 diagnosis. Safety data was not reported from this claims database.

For initiation injections, 72% (n = 732/1024) of second injections were administered within 37 days of the initial injection and 87% (n = 886/1024) were administered within 60 days.[20] For continuation injection, 86% (n = 3196/3715) were administered within 67 days of the previous injection and 96% (n = 3577/3715) were administered within 90 days. The overall median (IQR) PDC was 1.00 (0.96, 1.00); 87% (n = 1048/1202) had a PDC ≥ 0.9 and 97% (n = 1161/1202) had a PDC ≥ 0.8.

A subsequent analysis compared individuals receiving CAB LA (n = 805) to those receiving oral PrEP (n = 3220) (matched 1:4) with standardized mortality ratio (SMR) weighting applied after matching (CAB LA, n = 805; oral PrEP, n = 795); adherence and persistence was compared between the two groups.[21] A higher proportion of CAB LA users were adherent compared to oral PrEP users (SMR-weighted sample: odds ratio [OR; 95% CI] 2.20 [1.71-2.85]; $P < 0.001$; unadjusted sample: OR [95% CI] 2.12 [1.71-2.85]; $P < 0.001$). Median (95% CI) persistence was 374 (279-436) days for CAB LA and 225 (190-263) days for oral PrEP ($P < 0.001$). The risk of discontinuation was significantly lower in the CAB LA cohort in both the SMR-weighted and unadjusted samples (hazard ratio [95% CI]: 0.71 [0.62-0.82] and 0.79 [0.70-0.90], respectively).

USAID DISCOVER-HEALTH PROJECT (ZAMBIA)[8]

A multicenter, pilot implementation study of CAB LA in Zambia was conducted across 6 sites in 2 districts in a real-world setting. Participants were ≥ 16 years of age and at risk of HIV who anticipate being on PrEP for 12 months; 50% must have demonstrated oral PrEP adherence for at least 6 months and 50% new PrEP initiators. CAB LA adherence and discontinuation were evaluated.

A total of 609 participants were included; median age was 24 years, 56% female, and 70% were PrEP naïve. At month 1, 67% (n = 406) of participants were eligible for a second injection; at the second injection, 91% (n = 371) received the injection and 4% (n = 24) discontinued CAB LA. The most common reason for discontinuation was hepatitis B virus infection (n = 20). Two participants discontinued due to pregnancy, 1 due to severe rash, and 1 due to severe injection-site pain. Most participants switched to oral PrEP at discontinuation (n = 22); the remaining 2 participants started antiretroviral therapy after a positive HIV test. Additional information regarding the timing of HIV acquisition was not reported.

MOZAMBIQUE PILOT[9]

A pilot program in Nampula City offered CAB LA for PrEP to adolescent girls and young women aged 15-24 years at a single center. Rapid HIV tests were used for screening of HIV infection and sample from those with negative test had blood samples tested by polymerase chain reaction (PCR); these results were available at the second visit to determine CAB LA continuation.

From December 2024 to August 2025, 902 individuals were offered CAB LA and 490 (54%) initiated CAB LA. Most (69%) were age 15-19 years, 4% were pregnancy and 1% were breastfeeding. The return rate for the second CAB LA injection was 59% (n = 287/490).

Among participants with an initial negative HIV PCR, none seroconverted upon subsequent testing within 6 months of initiation. Two percent had testing positive on PCR from first visit and stopped CAB LA at the second visit.

No safety data was reported from this cohort.

IMPLEMENTATION STUDIES AND ADDITIONAL RWE COHORTS

Two phase 4, implementation-effectiveness studies were conducted to evaluate the integration of offering CAB LA for PrEP across various sites and populations in the US; key results from these studies are summarized in Table 2. Additional select RWE studies reported outcomes of CAB LA use for PrEP are summarized in Table 3.

Table 2. CAB LA Implementation Studies

Study Timepoint	Population	Sero-conversions	Persistence/ Discontinuation	Adherence
PILLAR[10] (US) Month 12	N = 201 Median (IQR) age: 35 (29, 44) years Black: 26% Hispanic: 38% Transgender men: 6% No oral PrEP (prior 6 months): 22%	0	Persistence: Month 6: 171 (85%) Month 12: 146 (73%)[a] Discontinuation: 55 (27%) -Due to AE: 11 (5%); injection site pain: 6[b]	On-time: 83-88%[c] Missed ≥ 1 injection: 3%[d]
EBONI[11] (US) Month 12	N = 163 Median (IQR)a age: 35 (29, 42) years Cisgender woman: 75% Transgender woman: 25% Black or AA: 100% Hispanic or Latine: 4% No oral PrEP (prior 6 months): 44%	0	Persistence: Month 6: 120 (74%) Month 12: 93 (57%) Discontinuation: 43% -Due to AE: 3 (2%)[e]	NR

[a] 72% (n = 144) completed all injections during the study; [b] Other reasons for discontinuation (n = 44): relocation (n = 9), insurance (n = 7), lost to follow-up (n = 7), sexual lifestyle change (n = 7), scheduling (n = 3), opted out of study procedures (n = 4), physician decision (n = 2), and other (n = 5). Two participants reported fatigue related to CAB LA. Serious adverse events were reported by one participant, unrelated to CAB LA. [c] Range of the proportion of injections administered ±7 days from the target date (based on the previous injection visit) throughout the study; 93% at Month 2 and decreased to 85% by Month 12; [d] Received either alterative PrEP (n = 5) or oral CAB (n = 1). [e] Overall drug-related adverse events: 5/163 (3%)

AE = adverse event; CAB LA = long-acting cabotegravir; IQR = interquartile range; NR = not reported; PrEP = pre-exposure prophylaxis

Table 3. Summary of Select Real-World Cohorts of CAB LA for PrEP[a]

Cohort, Design (Study period)	Population	Serocon-versions	Persistence/ Discontinuation	Adherence
Kaiser Permanente[12] Multicenter, retrospective cohort (May 23 2022-June 30, 2024)	N = 180 (prescribed CAB LA) Mean (SD) age: 39 (12) years Male: 92% White: 30% Black/AA: 19% H/o any bacterial STI: 45%	0	Persistence: 6 Months: 88% 12 Months: 75% Discontinuation: 35%[b]	N = 688 follow-up injections On-time: 87%[c] Early: 4% Late: 10%
CAN Community Health Network[13] (26 US clinics) Multicenter, retrospective cohort (December 2021-April 2023)	N = 293 (prescribed CAB LA) - Received at least 1 injection: 159 (52%) Median age: 36 years Male: 82% White, Non-Hispanic: 33% Black, Non-Hispanic: 29%	0	Persistence: 81% Discontinuation: 19%[d]	NR
Howard Brown Health[14] Single-center	N = 270 Median (IQR) age: 33 (28-40) years Male: 94%	1 (see text below for additional	Persistence: NR Discontinuation: 27 (10%)[e]	Delayed/missed follow-up injection: 8%

Cohort, Design (Study period)	Population	Seroconversions	Persistence/ Discontinuation	Adherence
retrospective cohort (July 1, 2022-December 31, 2023)	White, Non-Hispanic: 27% Black, Non-Hispanic: 25% Switched from oral PrEP: 72%	details)		
UCSD Owen Clinic[16] Single-center, retrospective cohort (January 1, 2022-December 31, 2023)	N = 187 Median (IQR) age: 33 (27, 49) Male: 91% White: 47% Non-Hispanic: 60% Previous oral PrEP: 77%	0	Persistence: NR Discontinuation: 39 (21%)[f]	NR
Whitman-Walker Health[17] Single-center, retrospective cohort (March 10, 2022-July 6, 2023)	N = 139 Median (range) age: 33 (21-65) Male: 95% White: 52% Transition from oral PrEP: 95%	0	Persistence: Second injection: 95% Third injection: 91% Discontinuation: N = 6[g]	On-time: Second injection: 91% Third injection: 63%
San Francisco Health System (Ward 86)[18] Retrospective cohort (March 2022-May 2024; follow-up through July 2024)	N = 111 Mean age: 37 years Male: 65% No prior PrEP use: 28% Mental health diagnosis: 57% Substance use: 51% Unstable housing: 36%	0	Persistence: 6 Months: 83% -Mean time on therapy: 221 days Discontinuation: N = 19[h]	N = 507 injections On-time: 85%[i]

[a] Limited safety information is available from the reported cohorts; [b] 12 had oral PrEP prescribed; 2 had oral prep during CAB LA use; [c] Percentage for all follow up injections; for first follow-up injection: 82%; subsequent follow-up injections: 88%; [d] Reasons for discontinuation: insurance coverage gaps or cost of copy (n = 7); side effects (n = 6); conflicts with work schedule (n = 2); not documented (n = 1); [e] Reasons for discontinuation: lost to follow up (n = 11); loss of coverage (n = 5); ISR (n = 5); moved away (n = 3); too busy (n = 2); HIV positive at initiation (n = 1); CAB LA at failure (n = 1); [f] Reasons for discontinuation: lost to follow up (n = 7); move/transfer care (n = 6); change in HIV risk (n = 4); insurance change (n = 2); multivariable logistic regression to evaluate factors associated with discontinuation was conducted: younger age (OR 1.05, 95% CI 1.01–1.11, *P* = 0.037) and non-patient assistance program coverage (OR 4.88, 95% CI 1.26–18.9, *P* = 0.022) were significantly associated with CAB LA discontinuation; [g] Reasons for discontinuation: injection site pain (n = 2); inconvenience (n = 2); stopping PrEP due to entering monogamous relationship (n = 2); 1 restarted injections, 4 transitioned to oral PrEP; [h] Reaons for discontinuation: low self perceived risk (n = 6); lost to follow-up (n = 6); adverse event (n = 4); 4 switched to oral PrEP, 15 did not restart any PrEP. Substance use (aOR 2.23; *P* = 0.017) and mental health diagnosis (aOR 5.36; *P* = 0.019) were associated with discontinuation. Additionally, those with prior but not current PrEP use compared to those with no prior PrEP were associated with discontinuation CAB LA (aOR 4.66; *P* = 0.036). [i] Mental health diagnosis was associated with late injections (adjusted odds ratio [aOR] 1.93; *P* = 0.04).

AA = African American; CAB LA = long-acting cabotegravir; H/o = history of; IQR = interquartile range; ISR = injection site reaction; NR = not reported; OR = odds ratio; PrEP = pre-exposure prophylaxis; SD = standard deviation; STI = sexually transmitted infection; UCSD = University of California San Diego

Howard Brown Health Seroconversion Additional Details

The patient who failed CAB LA was a 28-year-old, assigned male at birth; the patient was on TAF/FTC for 10 months prior to transition to CAB LA for PrEP to promote adherence.[22] The patient was sexually active with cis-gender men and reported condomless oral and anal sex with one primary partner (known HIV positive with resistance-associated mutations to nucleoside reverse transcriptase inhibitors [65R, 118I] and INSTI [92G]; undetectable HIV-1 RNA for 24 months on darunavir/cobicistat [DRV/c] plus dolutegravir [DTG]) and 20-30 unique partners per month; additionally, the patient recently started participating in receptive anal fisting intercourse. In the prior 6 months, the patient was diagnosed with secondary syphilis and anogenital MPOX. The patients' primary partner was off antiretroviral therapy (ART) for 2 months at the time of these diagnoses but was never documented to have detectable viremia.

After TAF/FTC was discontinued, CAB LA was given on Days 0, 27, and 91; Ag/Ab tests and HIV-1 RNA were negative at the first two injection visits.[22] On the day of the third dose, Ag/Ab test was negative and HIV-1 RNA was 1.48 log copies/mL. After 9 days, repeat Ag/Ab test was reactive and HIV-1 RNA was 1.30 log copies/mL. In addition to CAB LA, TAF/FTC was started for ART; HIV-1 sequencing was

unable to be performed. After 12 more days, Ag/Ab test was nonreactive and HIV-1 RNA was not detected; ART was changed to once daily DRV/c plus dolutegravir (DTG). Plasma CAB concentration 37 days after the last CAB LA injection was 1.180 µg/mL (between 4 x PA-IC_{90} [0.664 µg/mL] and 8 x PA-IC_{90} (1.33 µg/mL). On Day 191, Ag/Ab test was nonreactive, HIV-1 RNA was undetectable; the patient was continued on DRV/c plus DTG.

SEROPREP[23]

SeroPrEP is an observational study conducted in the US that enrolls people with evidence of possible HIV acquisition while using PrEP in routine care. An analysis was conducted to include individuals with detected HIV-1 RNA and non-reactive antigen/antibody test. Nine male participants were included: median (range) age was 33 (29-56) years, and BMI was 27 (22- 42) kg/m^2.

Seven participants had a single detectable HIV-1 RNA on clinical testing, however repeat testing (both clinical and research) showed no evidence of HIV. Three of these participants were temporarily started on ART and all 7 resumed or remained on PrEP. Another participant had a single detectable HIV-1 RNA on clinical testing as well as 2 research tests (RNA and DNA); this participant has remained on CAB LA with additional negative clinical HIV tests to date up to 22 months. The last participant had 2 detectable HIV-1 RNA on separate clinical samples (one qualitative and one with HIV-1 RNA < 20 copies/mL detected). ART was started rapidly, research tests showed no evidence of HIV. Subsequently, ART was paused for 5 months and 3 months later HIV was detected on 2 clinical RNA tests (290 copies/mL and 140 copies/mL) and ART was resumed.

ADDITIONAL STUDIES REPORTING RWE

Please see the reference list below for additional RWE studies.[24-26]

This information is scientific and non-promotional in nature and is not intended for further distribution.

This information is not intended to offer recommendations for using this product in a manner inconsistent with its approved labeling. Please consult the Prescribing Information. For ViiV Healthcare to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 877-844-8872.

Selection of references follows principles of evidence-based medicine and, therefore, references may not be all inclusive.

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