Clinical Outcomes at Month 24 After Initiation of Cabotegravir and Rilpivirine Long Acting (CAB+RPV LA) in an Observational Real-World Study (BEYOND)

EP0178

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IAS 2025 13–17 July

Key Takeaways

- BEYOND is one of the first real-world evidence studies of people with HIV-1 initiating long-acting cabotegravir and rilpivirine (CAB+RPV LA) in US clinics evaluating clinical and patient-reported outcomes
- CAB+RPV LA effectively maintained virologic suppression through Month 24, with low virologic failure rates and few discontinuations due to injection site reactions
- Adherence was high, with healthcare providers administering 88% of injections on time (post hoc analysis)

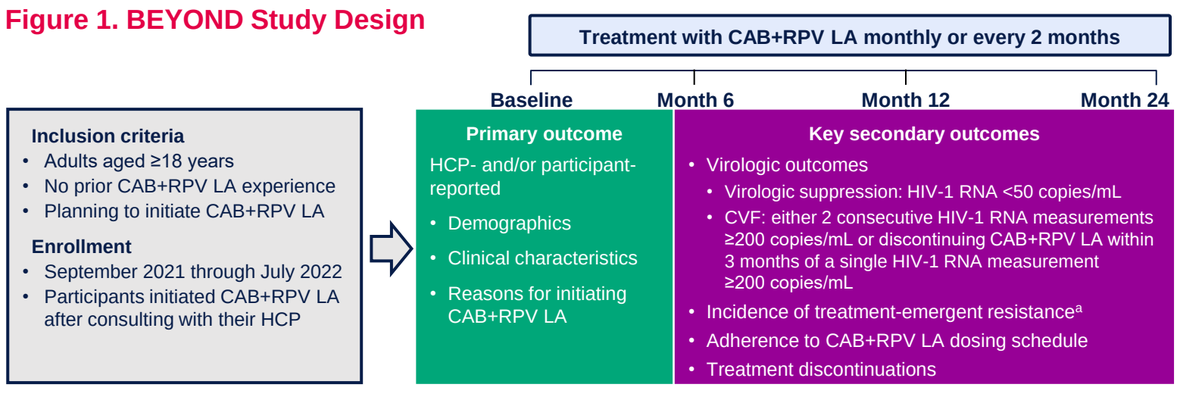
Background

- Cabotegravir and rilpivirine long-acting (CAB+RPV LA) is the first complete long-acting regimen recommended by treatment guidelines for maintaining virologic suppression[1,2]
- The phase 3/3b FLAIR, ATLAS, SOLAR, and CARES clinical trials previously demonstrated CAB+RPV LA is non-inferior to daily oral therapy[3-6]
  - Real-world data have also shown consistent effectiveness[7]
- BEYOND Month 12 results indicated that CAB+RPV LA is highly effective for maintaining virologic suppression in US real-world populations[8]
- Data on the long-term durability of ART regimens are important for clinically managing HIV[9]
- Here we describe 24-month clinical outcomes from the BEYOND study

Methods

- BEYOND is a 2-year, prospective observational study of utilization, outcomes, and experiences of people with HIV after initiating CAB+RPV LA (Figure 1)
- The healthcare provider (HCP) or designee recorded clinical outcomes data in electronic case report forms completed at baseline and Months 6, 12, and 24
- The study defined adherence using either the *initial* injection date (original analysis) or the *previous* injection date (post hoc analysis) as the basis for the subsequent injection date and the ±7-day window
- Data were stratified and analyzed according to treatment usage type: consistent with label (CWL) or inconsistent with label (IWL)
  - IWL classification was based on whether the participant:
    - Was not virologically suppressed (≥50 copies/mL) before initiating CAB+RPV LA
    - Reported prior virologic failure(s)
    - Had documented prior resistance to CAB or RPV

Figure 1. BEYOND Study Design



CVF, confirmed virologic failure; HCP, healthcare provider.
[a]HCPs reported resistance test results, if available, at baseline and at time of or after treatment discontinuation.

Results

Participant Demographics

- BEYOND enrolled 308 people with HIV-1 who initiated CAB+RPV LA across 27 US sites
  - 233 (76%) and 75 (24%) met study criteria for the CWL and IWL populations, respectively (Table 1)
- IWL population (not mutually exclusive)
  - Not virologically suppressed at initiation (n=28)
  - Previous virologic failure (n=8)
  - Documented prior resistance to CAB or RPV (n=47)

Table 1. Demographics and Baseline Characteristics

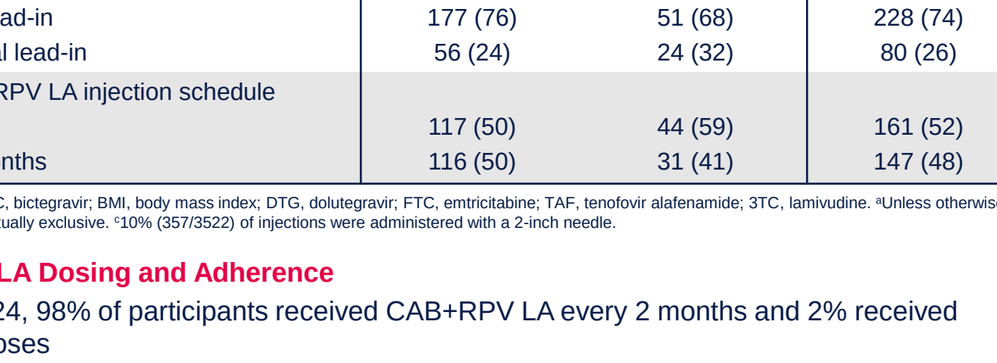
Parameter, n (%)[a]	CAB+RPV LA usage type: CWL (n=233)	IWL (n=75)	Total (N=308)
Age			
Mean (SD), years	45.8 (12.9)	46.1 (13.5)	45.9 (13.1)
≥50 years	89 (38)	32 (43)	121 (39)
Sex assigned at birth			
Male	205 (88)	63 (84)	268 (87)
Female	28 (12)	12 (16)	40 (13)
Race (self-identified)[b]			
White	115 (49)	32 (43)	147 (48)
Black or African American	91 (39)	28 (37)	119 (39)
Other races	60 (26)	27 (36)	87 (28)
BMI, median (range), kg/m^2	27.8 (16.9, 57.5)	27.9 (17.7, 45.7)	27.9 (16.9, 57.5)
BMI ≥30 kg/m^2[,c]	80 (34)	27 (36)	107 (35)
Insurance/Drug-coverage type			
Private health insurance	110 (47)	36 (48)	146 (47)
Medicaid	61 (26)	19 (25)	80 (26)
Medicare or Medigap	35 (15)	14 (19)	49 (16)
AIDS Drug Assistance Program/Ryan White	25 (11)	13 (17)	38 (12)
Other	25 (11)	5 (7)	30 (10)
Years since initiation of first ART	n=229	n=73	n=302
Median (range)	10.3 (0.1, 35.7)	9.7 (0.2, 35.0)	9.9 (0.1, 35.7)
Top 3 ART regimens before CAB+RPV LA initiation			
BIC/TAF/FTC	87 (37)	30 (40)	117 (38)
DTG/3TC	24 (10)	10 (13)	34 (11)
DTG/ABC/3TC	30 (13)	7 (9)	37 (12)
CAB+RPV LA initiation			
With oral lead-in	177 (76)	51 (68)	228 (74)
Without oral lead-in	56 (24)	24 (32)	80 (26)
Initial CAB+RPV LA injection schedule			
Monthly	117 (50)	44 (59)	161 (52)
Every 2 months	116 (50)	31 (41)	147 (48)

ABC, abacavir; BIC, bictegravir; BMI, body mass index; DTG, dolutegravir; FTC, emtricitabine; TAF, tenofovir alafenamide; 3TC, lamivudine. [a]Unless otherwise specified. [b]Not mutually exclusive. [c]10% (357/3522) of injections were administered with a 2-inch needle.

CAB+RPV LA Dosing and Adherence

- At Month 24, 98% of participants received CAB+RPV LA every 2 months and 2% received monthly doses
- Using the original adherence definition, HCPs administered 59% and 58% of injections on time (±7 days from the target treatment date) in the CWL and IWL groups, respectively
  - 30% and 25% were given early, and 11% and 17% were given late, respectively
- Using the adherence definition reflecting real-world practice (post hoc analysis), 89% and 85% of injections were given on time in the CWL and IWL groups, respectively (Figure 2)
- HCPs reported 3% (120/3700) of total expected injections through Month 24 were missed
  - Oral therapy covered 41% (49/120) of the missed injections
- The most common participant- and HCP-reported reasons for missing injections (besides "other" and "unknown") were insurance issues and forgotten/canceled appointments, respectively

Figure 2. Adherence to CAB+RPV LA Dosing Schedule Through Month 24 (Post Hoc Analysis)



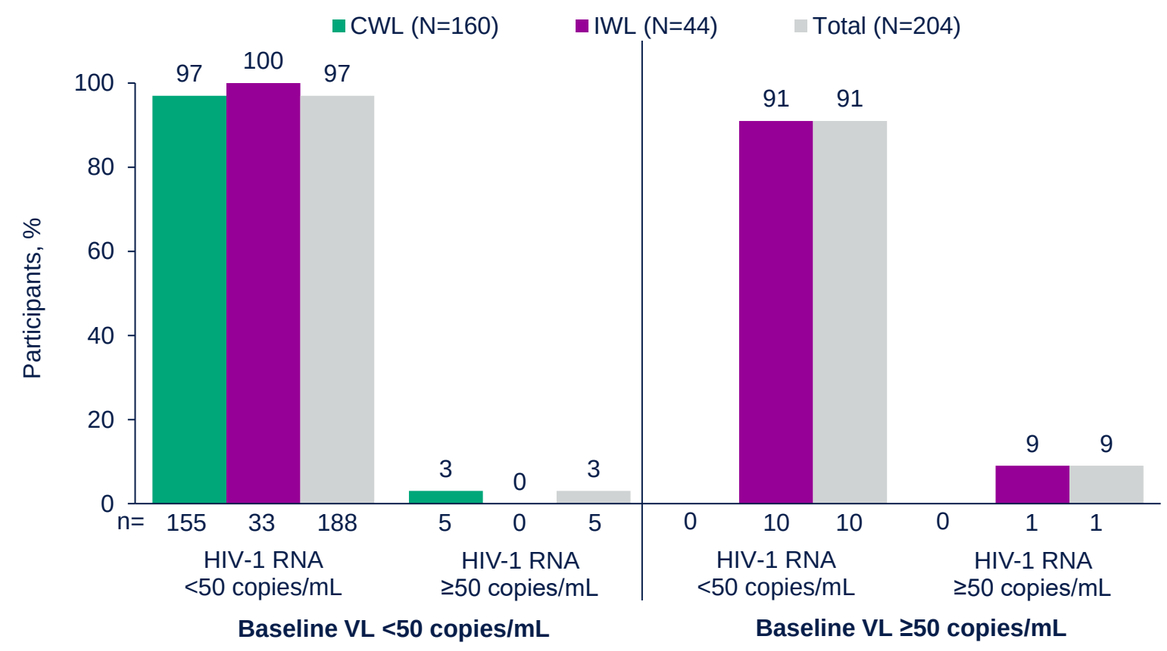
[a]After rounding, proportions in the CWL group total 101%. [b]On-time injections: within ±7 days from the target treatment date. [c]Early injections: >7 days before the target treatment date. [d]Late injections: >7 days after the target treatment date.

Virologic Outcomes

- Of participants with viral load <50 copies/mL at baseline, 95%, 97%, and 97% had a most recent viral load of <50 copies/mL at Months 6, 12, and 24, respectively (Figure 3)
- Of participants with viral load ≥50 copies/mL at baseline, 94%, 93%, and 91% had a most recent viral load of <50 copies/mL at Months 6, 12, and 24, respectively
- 6 participants (CWL, n = 2; IWL, n = 4) met CVF criteria through Month 24*
  - All CVFs occurred on or before Month 6
  - 3 participants with CVF (all in the IWL group) had resistance testing at the time of or after CAB+RPV LA discontinuation; all 3 had reported baseline and treatment-emergent mutations

*The study team determined that 1 CVF previously reported at Month 12 was an error[8]; the clinic collected the confirmatory viral load after the participant discontinued CAB+RPV LA.

Figure 3. Month 24 Virologic Outcomes Observed Based on Most Recent Viral Load[a]

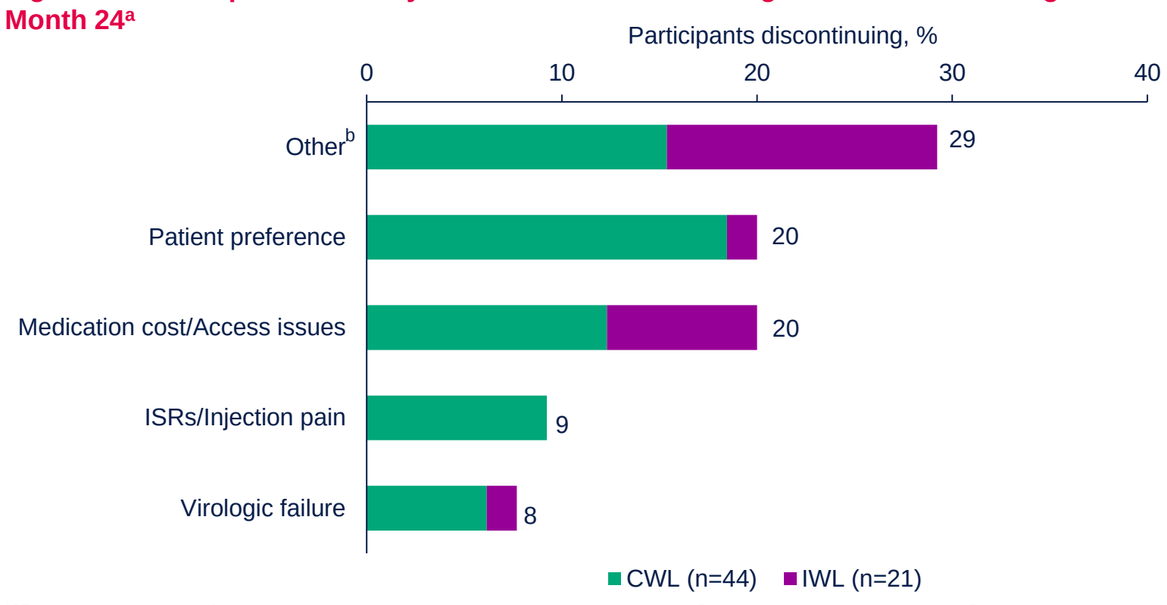


VL, viral load. [a]Population with VL data at both baseline and Month 24.

CAB+RPV LA Tolerability and Discontinuations

- 87/308 (28%) participants reported adverse events (AEs) through Month 24
  - 8 (3%) reported a serious AE
    - 1 participant reported 2 drug-related serious AEs
  - 14 (5%) reported a drug-related AE (excluding injection site reactions)
  - 31 (10%) reported an injection site reaction
- As of Month 24, 67 participants had discontinued CAB+RPV LA and an additional 30 had unknown treatment status
- The most common primary reasons for treatment discontinuation were "other" (29%), medication cost/access issues (20%), patient preference (20%), and injection site reactions/pain (9%; Figure 4)

Figure 4. HCP-Reported Primary Reasons for Discontinuing CAB+RPV LA Through Month 24[a]



ISR, injection site reaction. [a]Additional discontinuation reasons included resistance concerns (n=3), actual resistance development (n=2), clinic visit frequency (n=2), viremia (n=1), and CAB toxicity/intolerance (n=1). N=2 missing participant responses. [b]Other reasons not specified.

Conclusions

- Final results from BEYOND are consistent with CAB+RPV LA clinical trial results
  - In both the CWL and IWL groups, we observed high virologic suppression rates, low rates of CVF with treatment-emergent resistance, and few discontinuations due to injection site reactions/pain at Month 24
- HCPs administered 89% and 85% of injections on time in the CWL and IWL populations, respectively (post hoc analysis)
- Data support the long-term durability of CAB+RPV LA in real-world settings
- Participant perspectives on CAB+RPV LA through Month 24 in BEYOND are presented in Poster THPEB036

Acknowledgments: This study was funded by ViiV Healthcare. Editorial assistance and graphic design support for this poster were provided under the direction of the authors by Fingerpaint Medical and funded by ViiV Healthcare.

References: 1. Cabenuva [prescribing information]. ViiV Healthcare; 2025. **2.** Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV. 2024. **3.** Orkin et al. *N Engl J Med*. 2020;382:1124-1135. **4.** Ramgopal et al. *Lancet HIV*. 2023;10:e566-e577. **5.** Swindells et al. *N Engl J Med*. 2020;382:1112-1123. **6.** Kityo et al. *Lancet Infect Dis*. 2024;24:1083-1092. **7.** Sension et al. CROI 2025; San Francisco, CA. Poster 674. **8.** Dandachi et al. *Open Forum Infect Dis*. 2025;12:1-10. **9.** Lazarus et al. *HIV Med*. 2023;24(suppl 2):8-19.

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