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Clinical Outcomes at Month 6 After Initiation of Cabotegravir and Rilpivirine Long-Acting (CAB+RPV LA) in an Observational Real-World Study (BEYOND)

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Key Takeaways

- **BEYOND is one of the first real-world evidence (RWE) studies of CAB+RPV long-acting in US clinics describing the perspectives of healthcare providers (HCPs) and people with HIV (PWH) initiating CAB+RPV LA**
- **HCPs based in the United States reported patient request/ convenience as the primary reason for prescribing CAB+RPV LA**
- **Participants receiving CAB+RPV LA injections monthly or every 2 months experienced high rates of virologic suppression and low rates of confirmed virologic failures (CVFs) at Month 6 (M6) of the BEYOND study**
- **Adherence to the CAB+RPV LA dosing schedule was high, with only 4% of injections missed**

Introduction

- CAB+RPV LA is the first complete long-acting regimen for virologically suppressed people with HIV (PWH) recommended by treatment guidelines[1,2]
- Switching to CAB+RPV LA administered monthly or every 2 months demonstrated non-inferiority to daily oral antiretroviral therapy in the phase III/IIIb FLAIR, ATLAS, ATLAS-2M, and SOLAR studies[3-6]
- It is essential to understand utilization and clinical outcomes outside of randomized clinical trials among broader populations through real-world evidence (RWE) studies
- BEYOND is one of the first RWE studies evaluating the use of CAB+RPV LA in US clinics; here we describe the demographics and Month 6 (M6) clinical outcomes of patients initiating CAB+RPV LA in the United States

Methods

- BEYOND is a 2-year prospective, observational real-world study of utilization, outcomes, and experiences of PWH initiating CAB+RPV LA (monthly or every 2 months) across 27 US sites
- Participants were adults ≥18 years of age who had no prior treatment with CAB+RPV LA and initiated treatment under the discretion of their healthcare provider (HCP)
- Primary variables included
  - Reasons for initiating CAB+RPV LA self-reported by the participant and documented by the HCP
  - Demographic characteristics self-reported by participant and documented by the HCP
  - Clinical characteristics of participants upon initiation
- Key secondary outcomes included
  - Adherence to the CAB+RPV LA dosing schedule
  - Virologic outcomes, including suppression (defined as HIV-1 RNA measurement <50 c/mL) and confirmed virologic failure (CVF; defined as 2 consecutive plasma HIV-1 RNA measurements ≥200 c/mL or one HIV-1 RNA measurement ≥200 c/mL and discontinuation within 3 months of viral load ≥200 c/mL)
  - Incidences of treatment-emergent resistance
  - Discontinuations of CAB+RPV LA
- HCP-reported participant demographics, medical and treatment histories, and clinical outcomes from electronic case report forms (eCRFs) were assessed at baseline and M6
- Data were stratified and analyzed according to treatment usage type: consistent with label (CWL) or inconsistent with label (IWL), with IWL based on whether the participant (1) was not virologically suppressed (≥50 c/mL) before initiation of CAB+RPV LA, (2) had prior virologic failure(s) reported, and/or (3) had documented prior resistance to CAB or RPV

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References: 1. Panel on Antiretroviral Guidelines for Adults and Adolescents. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed August 8, 2023. **2.** Cabenuva [prescribing information]. ViiV Healthcare; 2021. **3.** Orkin et al. *N Engl J Med.* 2020;382:1124-1135. **4.** Overton et al. *Lancet.* 2021;396:1994-2005. **5.** Ramgopal et al. *Lancet HIV.* 2023. Accepted. **6.** Swindells et al. *N Engl J Med.* 2020;382:1112-1123.

Results

Participant Demographics

- A total of 308 PWH were enrolled from September 2021 to July 2022 and initiated CAB+RPV LA; mean age (SD) of participants was 45.9 (13.1) years, 87% (268/308) were male, and 48% (147/308) were White; 233 participants (76%) were determined to be in the CWL population, whereas 75 (24%) were determined to be in the IWL population (Table 1)
- Participants commonly had private health insurance (47% [146/308]), and most healthcare providers (HCPs) reported "patient request" as the primary reason for prescribing CAB+RPV LA (41% [125/308]; Figure 1)
- At the time of data cut-off for this analysis (January 10, 2023), 248 participants had reached the M6 time point

Table 1. Demographics and Baseline Characteristics of PWH Initiating CAB+RPV LA

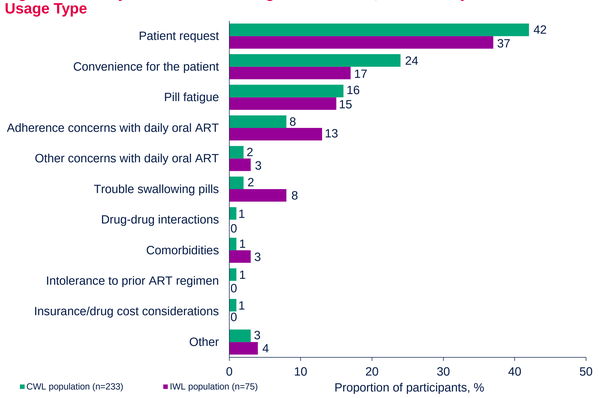
	CAB+RPV LA Usage Type		
Baseline Characteristic	**CWL (n=233)**	**IWL (n=75)**	**Total (N=308)**
Age			
Mean (SD), y	45.8 (12.9)	46.1 (13.5)	45.9 (13.1)
≥50 years, n (%)	89 (38)	32 (43)	121 (39)
Sex assigned at birth, n (%)			
Male	205 (88)	63 (84)	268 (87)
Female	28 (12)	12 (16)	40 (13)
Race (self-identified by participant), n (%)[a]			
White	115 (49)	32 (43)	147 (48)
Black or African American	91 (39)	28 (37)	119 (39)
Other race[b]	60 (26)	27 (36)	87 (28)
BMI			
Mean (SD), kg/m^2	29.0 (6.1)	28.6 (5.9)	28.9 (6.0)
Insurance/drug-coverage type, n (%)			
Private health insurance	110 (47)	36 (48)	146 (47)
Medicaid	61 (26)	19 (25)	80 (26)
Medicare or Medi-Gap	35 (15)	14 (19)	49 (16)
AIDS Drug Assistance Program/Ryan White	25 (11)	13 (17)	38 (12)
Other[c]	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, n (%)			
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)
Initiation of CAB+RPV LA, n (%)			
Oral lead-in use	177 (76)	51 (68)	228 (74)
No oral lead-in with CAB+RPV	56 (24)	24 (32)	80 (26)
Initial CAB+RPV LA injection schedule, n (%)			
Monthly	117 (50)	44 (59)	161 (52)
Every 2 months	116 (50)	31 (41)	147 (48)

BMI, body mass index; CWL, consistent with label; IWL, inconsistent with label; LA, long-acting; PWH, people with HIV.
[a]Not mutually exclusive. [b]Includes Native American, American Indian or Alaska Native (CWL, n=13; IWL, n=6), Asian (CWL, n=5; IWL, n=3), Native Hawaiian or other Pacific Islander (CWL, n=2; IWL, n=1), a race not listed (CWL, n=24; IWL, n=5), prefer not to answer (CWL, n=8; IWL, n=6). [c]Medicare-Medicaid plan (CWL, n=10; IWL, n=2), other coverage not listed (eg, a state-sponsored health plan, other government program, Indian Health Service; CWL, n=14; IWL, n=3), no healthcare or drug coverage of any type (CWL, n=1).

CAB+RPV LA Dosing and Adherence

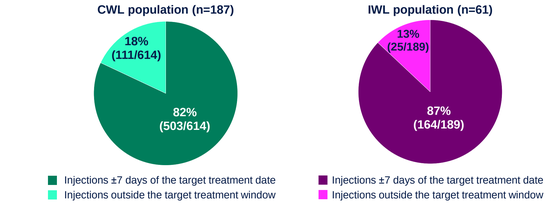
- Overall, 1043 doses of CAB+RPV LA were administered through the M6 data cut-off, with a median (range) of 4 (0-7) injections per participant
  - Injection needle length was reported for 1019 doses; 92% (935/1019) were administered via 1.5-inch needle (CWL, 92%; IWL, 90%) and all others were administered via 2-inch needle
- Of the 803 total injections given after the initial injection in the overall population, 667 (83%) occurred within ±7 days of the target treatment date and 136 (17%) were outside the target treatment window by a median of 4 days
  - Results were consistent across CAB+RPV LA usage type (Figure 2)
- Of 1087 total injections expected in the overall population, 44 (4%) injections (across 29 participants) were missed; of these, 22 (50%) injections were covered with oral therapy
- The most-cited reason (besides "other") for a missed injection was "patient forgot or canceled appointment" and "insurance/access issue" for CWL and IWL populations, respectively (Figure 3)

Figure 1. Primary Reason for Initiating CAB+RPV LA, Stratified by CAB+RPV LA Usage Type



CWL, consistent with label; HCP, healthcare provider; IWL, inconsistent with label; LA, long-acting.

Figure 2. HCP-Reported Participant Adherence to the CAB+RPV LA Dosing Schedule Stratified by CAB+RPV LA Usage Type



CWL, consistent with label; HCP, healthcare provider; IWL, inconsistent with label; LA, long-acting.

Figure 3. HCP-Reported Reasons for Missed Injection Stratified by CAB+RPV LA Usage Type

CWL, consistent with label; HCP, healthcare provider; IWL, inconsistent with label; LA, long-acting.

Virologic Outcomes

- Virologic data was available at both baseline and M6 for 189 participants (Table 2)
- For participants who were virologically suppressed at baseline, 96% (170/177) remained suppressed through M6 based on their most recent viral load test
- For participants who were not virologically suppressed at baseline, 92% (11/12) became suppressed by M6 based on their most recent viral load test; all 12 of those not suppressed at baseline, by definition, met inclusion criteria for the IWL population
- There were 4 participants (CWL, n=2; IWL, n=2) who met the definition of CVF
- NNRTI and INI drug resistance mutations were reported in 2 participants at the time of or following discontinuation (CWL, n=1; IWL, n=1)
  - CWL participant (no baseline resistance): NNRTI (L100I, K103NS), and INI (E138KA, G140SAC, Q148HRK)
  - IWL participant (documented resistance mutations at baseline: K103NS and PI resistance "other"): NNRTI (K103NS, E138KAGQ, Y181CIV), and INI (R263K)

Table 2. Virologic Outcomes at M6

	CAB+RPV LA Usage Type		
Category	**CWL (n=150)**	**IWL (n=39)**	**Total (n=189)**
Participants with viral load <50 c/mL at baseline	n=150	n=27	n=177
<50 c/mL, n (%)	146 (97)	24 (89)	170 (96)
≥50 c/mL, n (%)	4 (3)	3 (11)	7 (4)
Participants with viral load ≥50 c/mL at baseline	n=0	n=12	n=12
<50 c/mL, n (%)	NA	11 (92)	11 (92)
≥50 c/mL, n (%)	NA	1 (8)	1 (8)
	n=187	n=61	n=248
CVF[a]	2 (1)	2 (3)	4 (2)

CWL, consistent with label; CVF, confirmed virologic failure; IWL, inconsistent with label; LA, long-acting; PWH, people with HIV.
[a]Includes participants with at least 1 viral load test.

CAB+RPV LA Tolerability and Discontinuations

- A total of 64 adverse events were reported in 21% (52/248) of participants
  - The most common adverse event was injection site reactions, reported in 11% (26/248) of participants
- 10% (25/248) of PWH discontinued treatment with CAB+RPV LA (CWL, n=16; IWL, n=9) as of the data cut-off; HCP-reported primary reasons for discontinuation were
  - Injection site reactions/pain of injections (n=4)
  - Medication cost/access issues (n=4)
  - Patient preference (n=3)
  - Virologic failure (n=2)
  - Toxicity/intolerance to CAB+RPV LA (n=2)
  - Concerns about resistance (n=1)
  - Development of actual resistance (n=1)
  - Other reason (n=6)

Conclusions

- Participants initiating CAB+RPV LA had high rates of virologic suppression, low rates of CVFs, and low rates of discontinuation due to injection site reactions from the BEYOND study at M6
  - Treatment-emergent resistance was observed in 2 of 4 participants meeting CVF criteria
- Almost a quarter of PWH in this analysis initiated CAB+RPV LA IWL yet still demonstrated high rates of virologic suppression at M6; long-term safety and effectiveness in this population is unknown and more risk and benefit information may be warranted
- Interim results of CAB+RPV LA initiation in real-world settings within the United States are consistent with phase III/IIIb clinical trials

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