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1607. 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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Background. CAB+RPV LA is the first complete long-acting regimen for virologically suppressed people with HIV (PWH) and demonstrated non-inferiority to standard of care antiretroviral regimens in the Phase 3/3b trials FLAIR, ATLAS, ATLAS-2M, and SOLAR. Implementation of a provider administered regimen poses new delivery challenges and real-world evidence is essential to understand utilization and clinical outcomes. The BEYOND study describes the demographics and month 6 (M6) clinical outcomes of patients initiating CAB+RPV LA in the US.

Methods. BEYOND is a 2-year observational real-world study of utilization, outcomes, and experience of people with HIV (PWH) initiating CAB+RPV LA (monthly or every 2 months) across 30 US sites. Healthcare providers (HCPs) completed an electronic case report form (eCRF) at baseline and M6 to capture demographics, medical and treatment history, and clinical outcomes.

Results. A total of 308 PWH (Table 1) were enrolled between Sep 2021- Jul 2022 and initiated on CAB+RPV LA. As of the data cut-off for this analysis (Jan 2023), 248 PWH had reached M6 of which 25 were reported as having discontinued CAB+RPV LA. The most common HCP reported primary reason for initiating CAB+RPV LA was patient request (41%). At M6**,** of the 803 injections given after the first injections, 667 (83%) occurred within +/-7 days of the target treatment date and 136 (17%) were outside the target treatment window (median 4 days outside). Of 1087 total injections expected, 44 (4%) were missed; of these, 3 (7%) used oral CAB+RPV and 19 (44%) used other oral regimens to cover missed injections. Of 189 PWH with viral load data available at both baseline and M6 (Table 2), 181 (96%) had viral loads of < 50 copies/mL. Confirmed virologic failure (CVF) occurred in 4 (1.6%), including 1 who had missed injections. Resistance was reported in 2 PWH. Discontinuations due to drug intolerance/injection site reactions were reported in 6 PWH.

Table 1. Baseline Demographics of PWH initiating CAB+RPV LA

Age	**N=308**
Mean (SD), years	45.9 (13.1%)
≥50 years, %	121 (39.2%)
Sex assigned at birth	**N=308**
Female	40 (12.9%)
Male	268 (87.0%)
Race	**N=308**
White	134 (43.5%)
Black	103 (33.4%)
Other races	71 (23.1%)
Years since initiation of first antiretroviral regimen	**N=302**
Median (Min, Max)	9.9 (0.1, 35.7)
Number of ART regimens prior to CAB+RPV LA	**N=308**
1-2	172 (56%)
≥3	136 (44%)
Top 3 ART regimens prior to CAB+RPV LA initiation	**N=308**
Single tablet regimen	262 (85.1%)
Biktarvy (BIC/TAF/FTC)	117 (44.7%)
Dovato (DTG/3TC)	34 (13.0%)
Triumeq (DTG/ABC/3TC)	37 (14.1%)
Other regimens	46 (14.9%)
HCP Reported Primary Reason for initiating CAB+RPV LA	**N=308**
Patient request	125 (40.6%)
Convenience for the patient	69 (22.4%)
Pill fatigue	48 (15.6%)
Adherence concerns with daily oral ART	28 (9.1%)
Initiation of CAB +RPV LA	**N=308**
Oral lead in use	229 (74.4%)
No oral lead in with CAB+RPV	79 (25.6%)
Initial CAB+RPV LA Injection Schedule	**N=308**
Monthly	161 (52.3%)
Every 2 Month	147 (47.7%)

Table 2. Virologic Outcomes at Month 6

Virologic Outcomes at Month 6 by Baseline Viral Load	**N=189***
Among participants with viral load <50 copies/mL at baseline	N=177
<50 copies/mL at Month 6	170 (96.0%)
≥50 copies/mL at Month 6	7 (4.0%)
Among participants with viral load ≥50 copies/mL at baseline	N=12
<50 copies/mL at Month 6	11 (91.7%)
≥50 copies/mL at Month 6	1 (8.3%)
Confirmed virologic failures (CVF) at Month 6 **	4 (1.6%)

*189 PWH had viral load data available at both baseline and Month 6.

**Confirmed virologic failure was defined as 2 consecutive HIV-1 RNA viral loads ≥ 200 copies/ml or 1 HIV-1 RNA viral load ≥200 copies/mL followed by regimen discontinuation within 4 months of viral load ≥ 200 copies/mL.

Conclusion. The M6 results from real world initiation of CAB+RPV LA in the US are consistent with the Phase 3/3b clinical trials with high rates of virologic suppression, low rates of CVFs and treatment emergent resistance, and low rates of discontinuation due to drug intolerance.

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