High and Consistent Virologic Suppression Rates With Similar Adherence Were Observed Across Demographic Subgroups (Gender, Age, Race, BMI) Following 12 Months Switch of Cabotegravir and Rilpivirine Long-Acting Therapy in the Real-world BEYOND Study

Kaitlin Nguyen,[1] Cindy Garris,[1] Cathy Schubert,[1] Paula Teichner,[1] Deanna Merrill,[1] Ana Puga,[1] David Richardson,[2] Bintu Sherif,[2] Maria Reynolds,[2] Kate Nelson,[2] Laurie Zografos[2]

[1]ViiV Healthcare, Durham, NC, USA; [2]RTI Health Solutions, Research Triangle Park, NC, USA

Key Takeaways

- **BEYOND is one of the first real-world evidence studies reporting clinical and patient-reported outcomes among people with HIV-1 initiating long-acting cabotegravir plus rilpivirine (CAB+RPV LA) in clinics in the United States**
- **Through Month 12, CAB+RPV LA was highly effective for the maintenance of virologic suppression in real-world populations of people with HIV-1 across diverse demographic subgroups based on sex assigned at birth, age, race, and body mass index**
- **Low rates of virologic failure and high rates of adherence to injections across demographic subgroups further support CAB+RPV LA as a reliable long-acting treatment option for people with HIV-1**

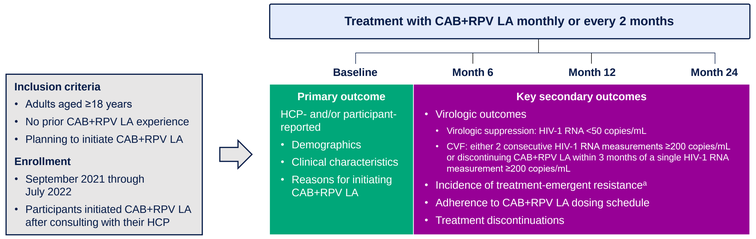
Introduction

- Long-acting cabotegravir plus rilpivirine (CAB+RPV LA) is the first complete long-acting regimen recommended for the maintenance of virologic suppression in people with HIV-1[1]
- The phase 3/3b FLAIR, ATLAS, and SOLAR clinical trials have demonstrated non-inferiority of CAB+RPV LA administered monthly or every 2 months to daily oral antiretroviral therapy[2-4]
- The effectiveness of CAB+RPV LA is also supported by real-world data[5-8]
- Month 12 results from the BEYOND study indicate that CAB+RPV LA is highly effective for the maintenance of virologic suppression in real-world populations in US clinics, with 91% of injections administered on time[9]
- Here we describe Month 12 clinical outcomes from the BEYOND study across different demographic subgroups, including sex assigned at birth, age, race, and body mass index (BMI)

Methods

- BEYOND is a 2-year, real-world, prospective observational study of utilization, outcomes, and experiences of people with HIV-1 initiating CAB+RPV LA monthly or every 2 months across 27 sites in the United States that enrolled participants between September 2021 and July 2022 (Figure 1)

Figure 1. BEYOND Study Design



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

- Electronic case report forms were completed at baseline and Months 6 and 12 by the healthcare provider or designee
  - Clinical outcomes data are reported herein for 272 (out of 308 enrolled) participants who completed Month 12 follow-up (data cutoff date: September 11, 2023)
- Clinical outcomes assessed included virologic suppression (HIV-1 RNA <50 copies/mL), confirmed virologic failure (CVF; defined as 2 consecutive HIV-1 RNA measurements ≥200 copies/mL or 1 HIV-1 RNA measurement ≥200 copies/mL followed by regimen discontinuation within 3 months), and adherence to the CAB+RPV LA dosing schedule
  - Adherence to the dosing schedule was evaluated using the previous injection date as the basis for the subsequent injection date and the ±7-day window
- Data were stratified by subgroups according to sex assigned at birth, age, race, and BMI
- Virologic outcomes data were also 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 (1) was not virologically suppressed (≥50 copies/mL) before initiating CAB+RPV LA, (2) had reported prior virologic failure(s), and/or (3) had documented prior resistance to CAB or RPV

Results

Participant Demographics

- 308 people with HIV-1 were enrolled and initiated CAB+RPV LA (Table)
- 39% of participants were aged ≥50 years, 87% were assigned male at birth, 48% were White, 39% were Black, 24% were other races, and 35% had a BMI ≥30 kg/m^2

Table. Baseline Characteristics and Demographics

Parameter, n (%)[a]	Total (N=308)
Sex assigned at birth	
Male	268 (87)
Female	40 (13)
Current gender identity	
Male	256 (83)
Female	40 (13)
Transgender woman	5 (2)
Transgender man	1 (<1)
Non-binary	6 (2)
Age, years	
Median (range)	45 (18-80)
18 to <50	187 (61)
≥50	121 (39)
Race[b]	
Asian	8 (3)
Black or African American	119 (39)
Native American, American Indian, or Alaska Native	19 (6)
Native Hawaiian or Other Pacific Islander	3 (1)
White or Caucasian	147 (48)
Race(s) not listed	29 (9)
Prefer not to answer	14 (5)
Ethnicity	
Hispanic/Latin American	68 (22)
Non-Hispanic/Latin American	220 (71)
Prefer not to answer	20 (7)
BMI, kg/m^2	
<30	201 (65)
30-39	88 (29)
≥40	19 (6)
CAB+RPV LA usage type	
CWL	233 (76)
IWL	75 (24)
Years since initiation of first ART regimen	n=302[c]
Median (range)	9.9 (0.1-35.7)
Healthcare provider–reported relevant social determinant of health (last 5 years to present), >5%	
Comorbidities	70 (23)
Adherence issues	58 (19)
Mental health conditions	47 (15)
Polypharmacy/Multiple medications	44 (14)
Health insurance issues or changes	33 (11)
Substance use[d]	30 (10)
Affordability of HIV medications	22 (7)
Job instability	19 (6)
Homelessness/Housing instability	19 (6)
Difficult work and/or family schedule	18 (6)

ART, antiretroviral therapy. [a]Unless otherwise stated. [b]Not mutually exclusive. [c]Missing data for n=6. [d]For example, injection drug use and alcohol misuse.

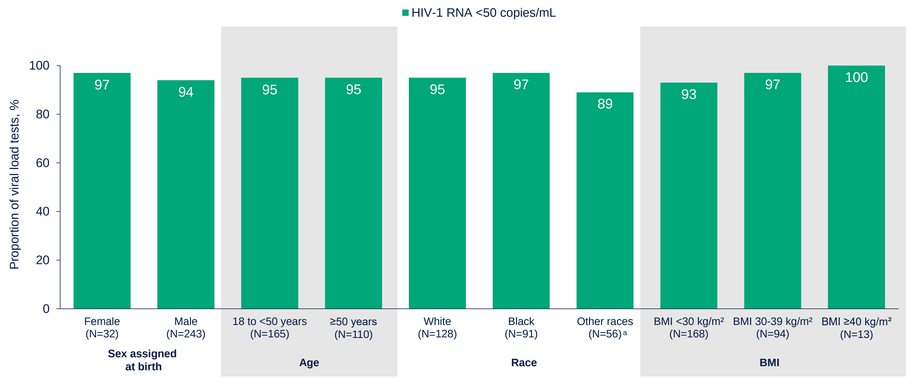
Virologic Outcomes

- At Month 12, high virologic suppression rates (89%-100%) were observed across all subgroups (Figure 2)
  - Among participants with BMI <30 kg/m^2 and baseline viral load <50 copies/mL, virologic suppression at Month 12 was observed in 98% (96/98) of those who were CWL and 80% (12/15) of those who were IWL
- 7 CVFs occurred through Month 12, with 6/7 occurring at or before Month 6
  - Of the 7 participants with CVF through Month 12, 5 were in the IWL group, 5 were assigned male at birth, 5 were White, 1 was Black, 5 were aged <50 years, and 5 had BMI <30 kg/m^2
  - 3 participants with CVF had resistance testing at the time of or after CAB+RPV LA discontinuation, all in the IWL group; all 3 had reported baseline resistance and treatment-emergent mutations
  - 4/5 participants with CVF through Month 12 and BMI <30 kg/m^2 were IWL

Adherence

- Adherence was high and similar across all demographic subgroups, with the majority of injections given within the ±7-day dosing window (Figure 3)

Figure 2. Virologic Outcomes Observed at Month 12 by Sex Assigned at Birth, Age, Race, and BMI (Enrolled Population)



Number of viral load tests between Month 6 and 12 is shown. [a]Includes Asian; Native American, American Indian, or Alaska Native; Native Hawaiian or Other Pacific Islander; race(s) not listed; and prefer not to answer.

Figure 3. Adherence Through Month 12 by Sex Assigned at Birth, Age, and Race

[a]The proportion of injections given within vs outside of the ±7-day target treatment window is shown for each subgroup. [a]Includes Asian; Native American, American Indian, or Alaska Native; Native Hawaiian or Other Pacific Islander; race(s) not listed; and prefer not to answer.

Conclusions

- These findings support the effectiveness of CAB+RPV LA in maintaining virologic suppression across diverse demographic subgroups of people with HIV-1 in real-world clinical settings
- Consistently high virologic suppression rates (>89%), a low rate of CVFs (2%), and high adherence rates (>87% of all injections given on time) were observed across demographic subgroups through Month 12 in the BEYOND study
- These results underscore the potential of CAB+RPV LA as a reliable long-acting treatment option for people with HIV-1

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 (formerly MedThink SciCom) and funded by ViiV Healthcare.

References: 1. Cabenuva [prescribing information]. ViiV Healthcare; 2025. **2.** Orkin et al. *N Engl J Med*. 2020;382:1124-1135. **3.** Ramgopal et al. *Lancet HIV*. 2023;10:e566-e577. **4.** Swindells et al. *N Engl J Med*. 2020;382:1112-1123. **5.** González-Cordón et al. CROI 2025; San Francisco, CA. Poster 678. **6.** Sension et al. *Infect Dis Ther*. 2023;12:2807-2817. **7.** Sension et al. CROI 2025; San Francisco, CA. Poster 674. **8.** Sax et al. CROI 2025; San Francisco, CA. Poster 675. **9.** Schneider et al. AIDS 2024; Munich, Germany. Poster THPEB099.

Presenting author: Kaitlin Nguyen; kaitlin.p.nguyen@viivhealthcare.com