The Power of Choice: Strong Preference for CAB+RPV LA Following Rapid Suppression With DTG/3TC in ART-Naive People Living With HIV

Poster EP0170

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IAS 2025 13–17 July

Key Takeaways

- **In the Phase 3b VOLITION study, initial use of dolutegravir and lamivudine (DTG/3TC) provided a route for antiretroviral therapy (ART)-naive individuals to quickly achieve virologic suppression and facilitated an early switch to long-acting injectable cabotegravir plus rilpivirine (CAB+RPV LA).**
- **The vast majority of eligible participants chose to switch to CAB+RPV LA at Day of Choice (DoC), after virologic suppression with DTG/3TC was achieved.**
- **Participants who chose to switch to CAB+RPV LA cited convenience and psychological benefits as reasons for switching, and felt that having the option to switch provided greater freedom and more autonomy in their treatment.**
- **Empowering ART-naive people with HIV (PWH) with the opportunity to switch to CAB+RPV LA immediately after achieving rapid virologic suppression with DTG/3TC allowed participants to choose a treatment option that best met their individualized needs.**

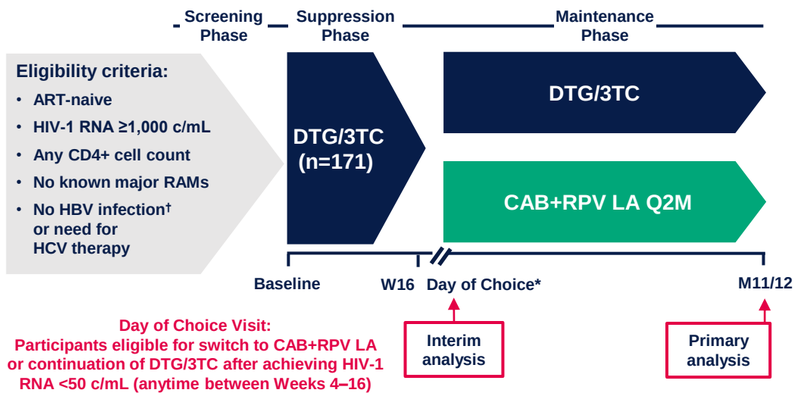
Background

- CAB+RPV LA is the first and only complete LA injectable regimen approved for use in virologically suppressed PWH.[1,2]
- CAB+RPV LA and DTG/3TC are two-drug regimens with different modalities and dosing frequencies, allowing for greater patient choice.
- In real-world and clinical studies, CAB+RPV LA has demonstrated:
  - Durable efficacy and a low virologic failure rate,[3–10] with greater treatment satisfaction and preference over daily oral therapy.[11–13]
  - Improvements in psychological challenges including fear of disclosure, anxiety surrounding adherence, and the reminder of HIV status.[11]
- The VOLITION (NCT05917509) study evaluated efficacy, safety, and participant-reported outcomes following the option to switch from DTG/3TC to CAB+RPV LA immediately after attaining virologic suppression.
- We present patient-experience data before and after switch from DTG/3TC to CAB+RPV LA at DoC.

Methods

VOLITION Study Design

Phase 3b, multicenter, non-randomized, parallel-group, open-label, implementation-effectiveness study



*Participants will proceed to Day of Choice at their next study visit following the first plasma HIV-1 RNA result <50 c/mL (Week 4 at the earliest but no later than Week 16). Participants must be suppressed <50 c/mL in order to qualify for option switch to CAB+RPV LA. Exclusion criteria for switch included: treatment-emergent ALT ≥5×ULN; or ALT ≥3×ULN and bilirubin ≥1.5×ULN (with >35% direct bilirubin) and pregnancy. †Participants positive for HBsAg were excluded. Participants negative for anti-HBs but positive for anti-HBc were excluded only if HBV DNA was detected.
3TC, lamivudine; ALT, alanine aminotransferase; anti-HBs, hepatitis B surface antibody; ART, antiretroviral therapy; CAB, cabotegravir; DTG, dolutegravir; HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; LA, long-acting; M, month; Q2M, every 2 months; RAM, resistance-associated mutation; RPV, rilpivirine; ULN, upper limit of normal; W, week.

- The VOLITION study evaluated initial viral suppression with DTG/3TC up to ~16 weeks followed by participant-determined optional switch to CAB+RPV LA dosed every 2 months or continuation of DTG/3TC through Month 11/12.
- The co-primary study endpoints were:
  - Time to virologic suppression (HIV-1 RNA <50 c/mL) from baseline.
  - The proportion of participants with HIV-1 RNA <50 c/mL per Snapshot algorithm at Month 11 (CAB+RPV LA).
- We present participant experience data which were evaluated at baseline and DoC using questionnaires; outcomes included:
  - Choice of regimen and reasons for switching
  - Psychological challenges related to HIV treatment (DoC only)
  - Perceptions, barriers, and facilitators of switching treatment
  - Acceptability and feasibility of switching (Acceptability of Intervention Measure [AIM] and Feasibility of Intervention Measure [FIM]) (DoC only)*
  - Emotions or feelings related to HIV diagnosis and status.

*AIM and FIM are rated on a 1–5 Likert scale: 1 = "completely disagree"; 2 = "disagree"; 3 = "neither agree nor disagree"; 4 = "agree"; 5 = "completely agree".

Results

VOLITION Enrolled a Diverse Population of ART-Naive Adults With HIV-1

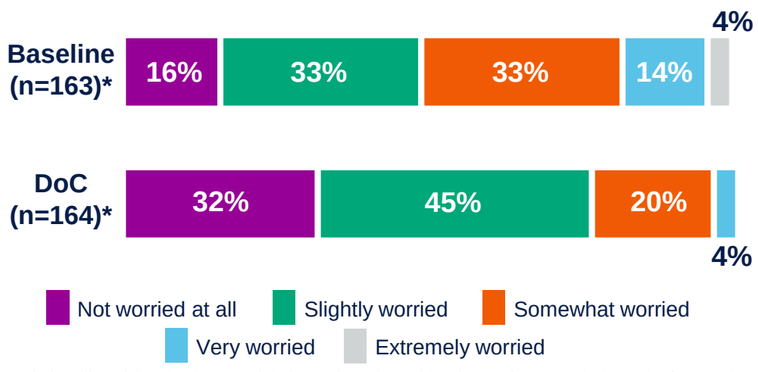
Parameter	DTG/3TC (n=171)
Median age, years (range)	31 (18–70)
≥50 years, n	18 (11)
Women (self-identified gender), n (%)	45 (26)
Race, n (%)	
Black or African American	51 (30)
White	106 (62)
Other races*	7 (4)
Not reported or unknown	7 (4)
Hispanic/Latinx ethnicity, n (%)	88 (51)
Region, n (%)†	
North America	78 (46)
Europe	47 (27)
South America	46 (27)
CD4+, cells/mm^3, median (IQR)	396 (252, 543)
Median BMI, kg/m^2 (IQR)	24.4 (21.7, 29.1)
≥30 kg/m^2, n (%)	34 (20)

*Other race participants: Multiple, n=3; Asian, n=4.
†Argentina (n=28), Canada, (n=9), Chile (n=18), France (n=9), Germany (n=5), Italy (n=16), Spain (n=17), United States (including Puerto Rico; n=69).
3TC, lamivudine; ART, antiretroviral therapy; DTG, dolutegravir; IQR, interquartile range.

- Overall, 171 participants enrolled in the study and initiated DTG/3TC; 11% were ≥50 years, 26% were women, 30% were Black or African American, and 51% were Hispanic/Latinx.
- At baseline, 85% (n=101/119) of participants who had considered what treatment they would choose at DoC expressed an interest in switching to CAB+RPV LA therapy.
- Median (95% confidence interval) time to suppression with DTG/3TC was 4.1 (4.1–4.3) weeks (see Poster WEPEB033 for further details on virologic outcomes with DTG/3TC).[14]

The Proportion of Participants Who Reported Worry About Their HIV Diagnosis Decreased By DoC

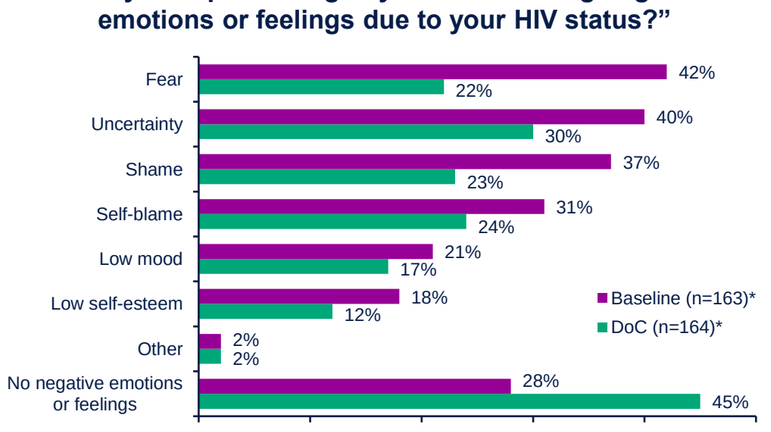
"How do you feel about your HIV diagnosis?"



*Includes all participants who completed questionnaires within the window at each timepoint (n=8 and n=7 participants had missing data at baseline and DoC, respectively).
DoC, Day of Choice.

Fewer Participants Reported Experiencing Negative Emotions or Feelings Due to Their HIV Status at DoC vs. Baseline

"Are you experiencing any of the following negative emotions or feelings due to your HIV status?"



*Participants could select more than one response. Includes all participants who completed questionnaires within the window at each timepoint (n=8 and n=7 participants had missing data at baseline and DoC, respectively). DoC, Day of Choice.

Participants Valued Being Empowered With the Option to Switch and its Associated Advantages

"How does it feel to be given a choice about your future HIV treatment?" (n=155)*

- **72%** "I am happy to know there are options for future treatment to match my lifestyle"
- **55%** "It provides me with an option to suit my needs and daily life"
- **53%** "It gives me hope for the future"

"What are the advantages of having the option of switching from a daily pill for HIV treatment to a LA HIV injection treatment to keep your HIV undetectable (virally suppressed)?" (n=155)*

- **70%** "The option to switch fits my life better"
- **67%** "Freedom to travel without concern about keeping my HIV undetectable"
- **58%** "I get more of a say/more autonomy in my treatment"

*Includes all participants who reported that they were given the choice to switch from DTG/3TC to CAB+RPV LA. Participants could select more than one response. The three most commonly reported answers are provided.
3TC, lamivudine; CAB, cabotegravir; DTG, dolutegravir; LA, long-acting; RPV, rilpivirine.

- At DoC, participants found the option of switching to CAB+RPV LA highly acceptable (mean [SD] AIM: 4.4 [0.78]) and the act of switching feasible (mean [SD] FIM: 4.3 [0.89]).

The Vast Majority of Eligible Participants Chose to Switch to CAB+RPV LA at DoC

- Overall, 129 participants switched to CAB+RPV LA at DoC:
  - Median age (range) was 31.0 (18-67) and 10% were ≥50 years.
  - 26% were women, 33% were Black or African American, and 51% were Hispanic/Latinx.
  - 22% had a BMI ≥30 kg/m^2.

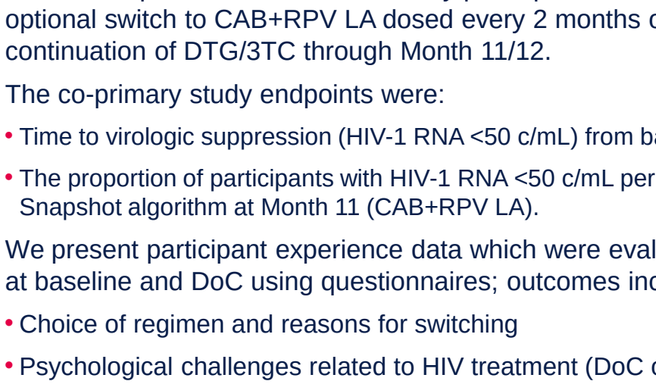
Despite Achieving Virologic Suppression, Participants Choosing CAB+RPV LA Reported Psychological Challenges at DoC

*Includes only participants who switched from DTG/3TC to CAB+RPV LA (n=129; n=2 participants had missing data). 3TC, lamivudine; CAB, cabotegravir; DoC, Day of Choice; DTG, dolutegravir; LA, long-acting; RPV, rilpivirine

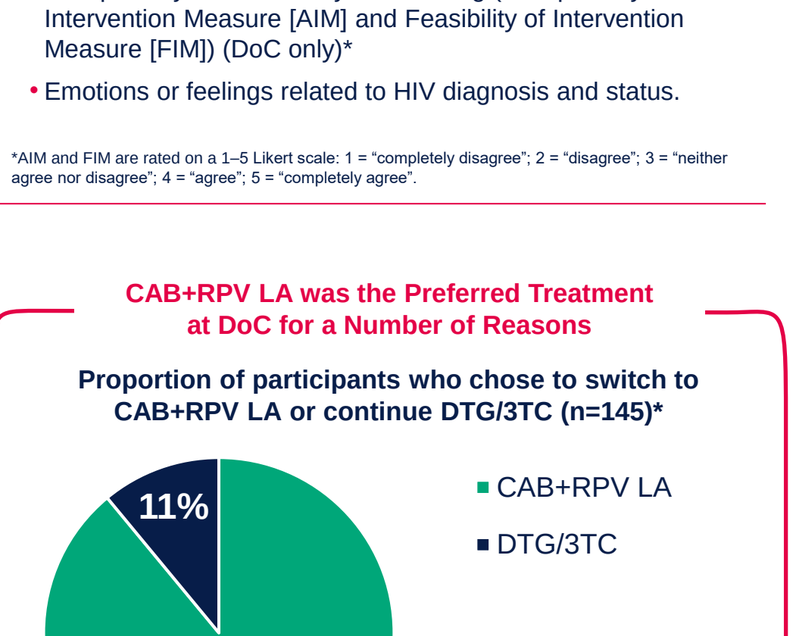
- At DoC, 65% (n=83/127) of participants reported "always"/"often" experiencing at least one psychological challenge.

CAB+RPV LA was the Preferred Treatment at DoC for a Number of Reasons

Proportion of participants who chose to switch to CAB+RPV LA or continue DTG/3TC (n=145)*



Top five participant-reported reasons for switching to CAB+RPV LA (n=129)†



*Four participants withdrew from the study prior to DoC: adverse event (n=1), lost to follow-up (n=1), physician decision (n=2); 22 were ineligible to switch: HIV-1 RNA not suppressed (n=15), HIV subtype A1/A6 (n=1), other (n=6). †Responses are not mutually exclusive. The most common reasons why participants chose to remain on DTG/3TC included believing that remembering to take the pill daily was easy or it will be easy to take their daily pill for HIV treatment daily (31%, n=13/42) and not liking getting injections (17%, n=7/42).
3TC, lamivudine; CAB, cabotegravir; DoC, Day of Choice; DTG, dolutegravir; LA, long-acting; RPV, rilpivirine.

Conclusions

- In VOLITION, the majority of participants felt that being given the choice to switch to CAB+RPV LA provided greater freedom and more autonomy in their treatment.
- Despite achieving virologic suppression, most participants (65%) who chose CAB+RPV LA reported at least one psychological challenge at DoC, emphasising the importance of parameters beyond traditional clinical measures when making treatment decisions.
- Most participants (85%) expressed an interest in switching to CAB+RPV LA at baseline; the vast majority of eligible participants (89%) chose to switch to CAB+RPV LA at DoC and found switching highly acceptable and feasible.
- Not having to worry about missing a dose each day, not having to carry medication, and convenience were highlighted by participants as key reasons for choosing to switch to CAB+RPV LA.
- Empowering ART-naive PWH with the opportunity—through offering LA therapy and shared decision-making—to switch to CAB+RPV LA immediately after achieving rapid virologic suppression with DTG/3TC allowed participants to choose a treatment option that best met their individualized needs, which is essential for treatment success and quality of life.

Acknowledgments: The authors thank everyone who has contributed to the VOLITION study, including all patient participants and their families, and the VOLITION clinical investigators and their staff. This study was funded by ViiV Healthcare. Editorial assistance was provided by Poppy Mashilo at Nucleus Global, with funding provided by ViiV Healthcare.

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