Who's in VOGUE: A Head-to-Head Clinical Trial of Dolutegravir/Lamivudine Versus Bictegravir/Emtricitabine/Tenofovir Alafenamide in Adults Naive to Antiretroviral Therapy, Including Those With High Viral Loads

WEPEB094

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AIDS 2026 26–31 July

Key Takeaways

- VOGUE is the first international head-to-head clinical trial of DTG/3TC vs BIC/FTC/TAF as first-line regimens, providing clinicians with comparative data for adults with HIV-1 naive to treatment
- The study enrolled a broad and clinically relevant population, including individuals with high (≥100,000 c/mL) or very high (≥500,000 c/mL) VLs and low CD4+ cell counts (<200 cells/mm^3)
- The study was conducted using a test-and-treat approach, with treatment initiated prior to the availability of resistance test results; few participants (≤1%) were excluded due to active HBV or RAMs at baseline

VOGUE Study

Plain Language Summary

- VOGUE is the first study to directly compare 2 commonly used HIV regimens, DTG/3TC and BIC/FTC/TAF, among people starting treatment for the first time
- The trial enrolled a broad group of people, including those with more advanced HIV or higher levels of virus in the blood
- Few people were unable to participate in the study because of HBV (<1%) or resistance mutations (1%), suggesting that DTG/3TC can be started quickly after diagnosis, similar to real-world care

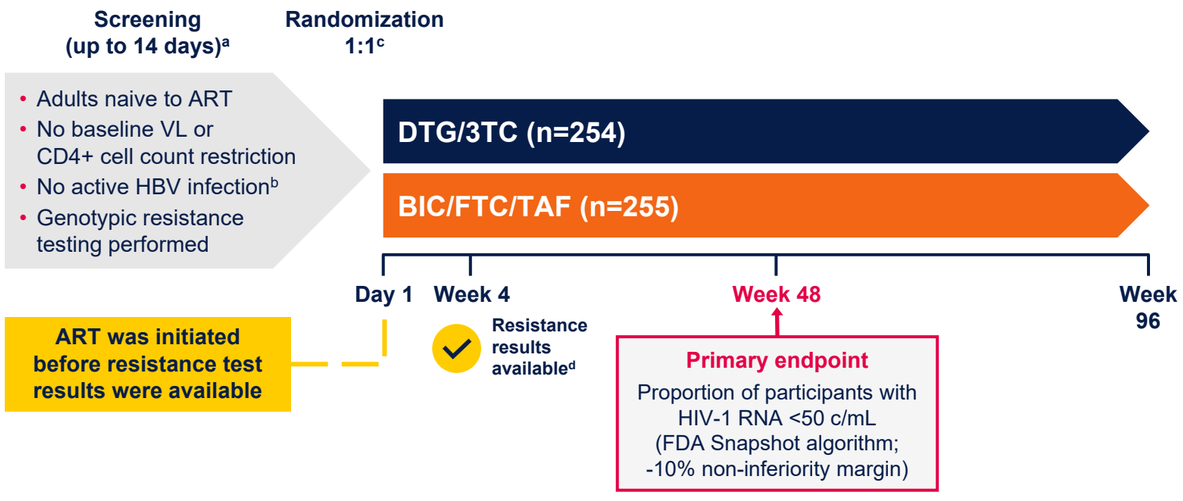
Background

- Dolutegravir/Lamivudine (DTG/3TC) is an extensively studied and guideline-recommended oral 2-drug regimen for adults with HIV-1 initiating antiretroviral therapy (ART)[1-9]
- Previously, there were no randomized controlled trials comparing DTG/3TC with the 3-drug regimen bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) as first-line therapy among people naive to ART
- VOGUE is the first head-to-head clinical trial comparing DTG/3TC with BIC/FTC/TAF among individuals starting ART in a test-and-treat setting, with no baseline viral load (VL) or CD4+ cell count restrictions
  - This analysis describes the baseline demographics of the VOGUE study population

Methods

- VOGUE (NCT05979311) is a phase 3b, randomized, non-inferiority study evaluating DTG/3TC vs BIC/FTC/TAF as initial ART in adults with HIV-1 (Figure 1)

Figure 1. Study Design



FDA, US Food and Drug Administration; HBcAb, hepatitis B core antibody. [a]Extenuating situations could delay the Day 1 visit beyond 14 screening days. [b]Participants with immunity to HBV, including those with isolated HBcAb positivity without detectable HBV DNA, were not excluded. Vaccination according to local guidelines was encouraged for participants naive to or not vaccinated against HBV. [c]Stratified by plasma HIV-1 RNA (<100,000 vs ≥100,000 c/mL) and CD4+ cell count (<200 vs ≥200 cells/mm^3) at screening. [d]Participants with major RAMs to integrase strand transfer inhibitors, 3TC, FTC, or TAF were required to discontinue study treatment.

- Participants were screened at 63 sites in 17 countries across 4 continents (Figure 2)
- To reflect clinical practice settings, treatment was initiated before baseline genotype resistance results were known
- Baseline characteristics are descriptively summarized

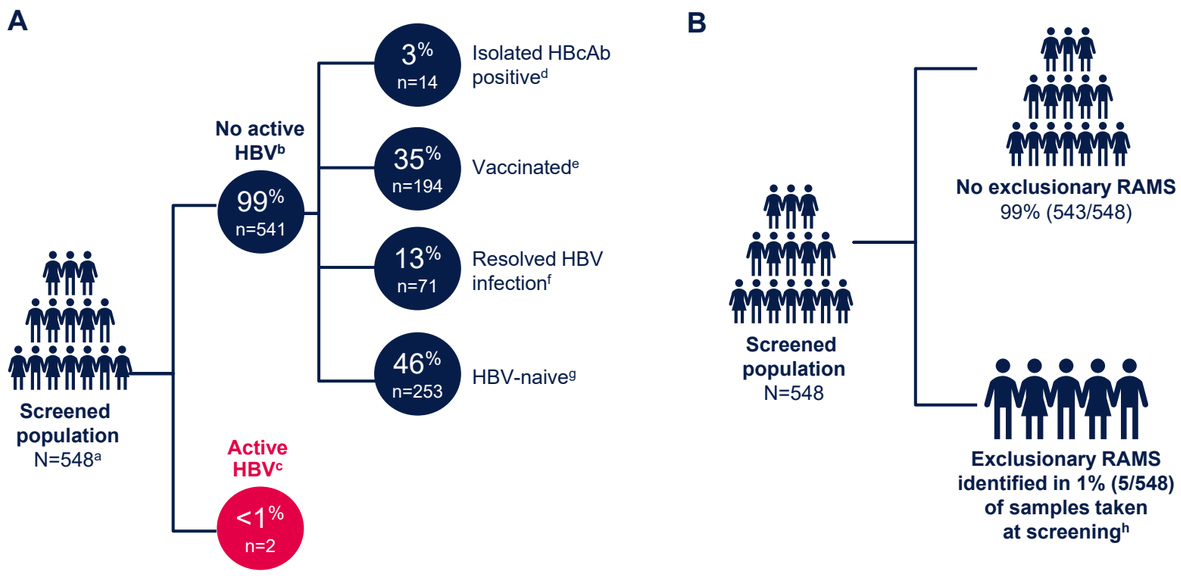
Figure 2. Participating Countries

Results

Screening and Enrollment

- Of 548 participants screened, 509 were randomly assigned to receive DTG/3TC or BIC/FTC/TAF
  - Screening failure rate was low (6% [34/548])
  - Active hepatitis B virus (HBV; 2/548) and exclusionary resistance-associated mutations (RAMs; 5/548) were identified in ≤1% of screened participants (Figure 3)
- The median (interquartile range) time between screening and enrollment was 10 (8-14) days

Figure 3. Low Exclusion Rate due to (A) Active HBV and (B) Exclusionary RAMs in Screening Samples

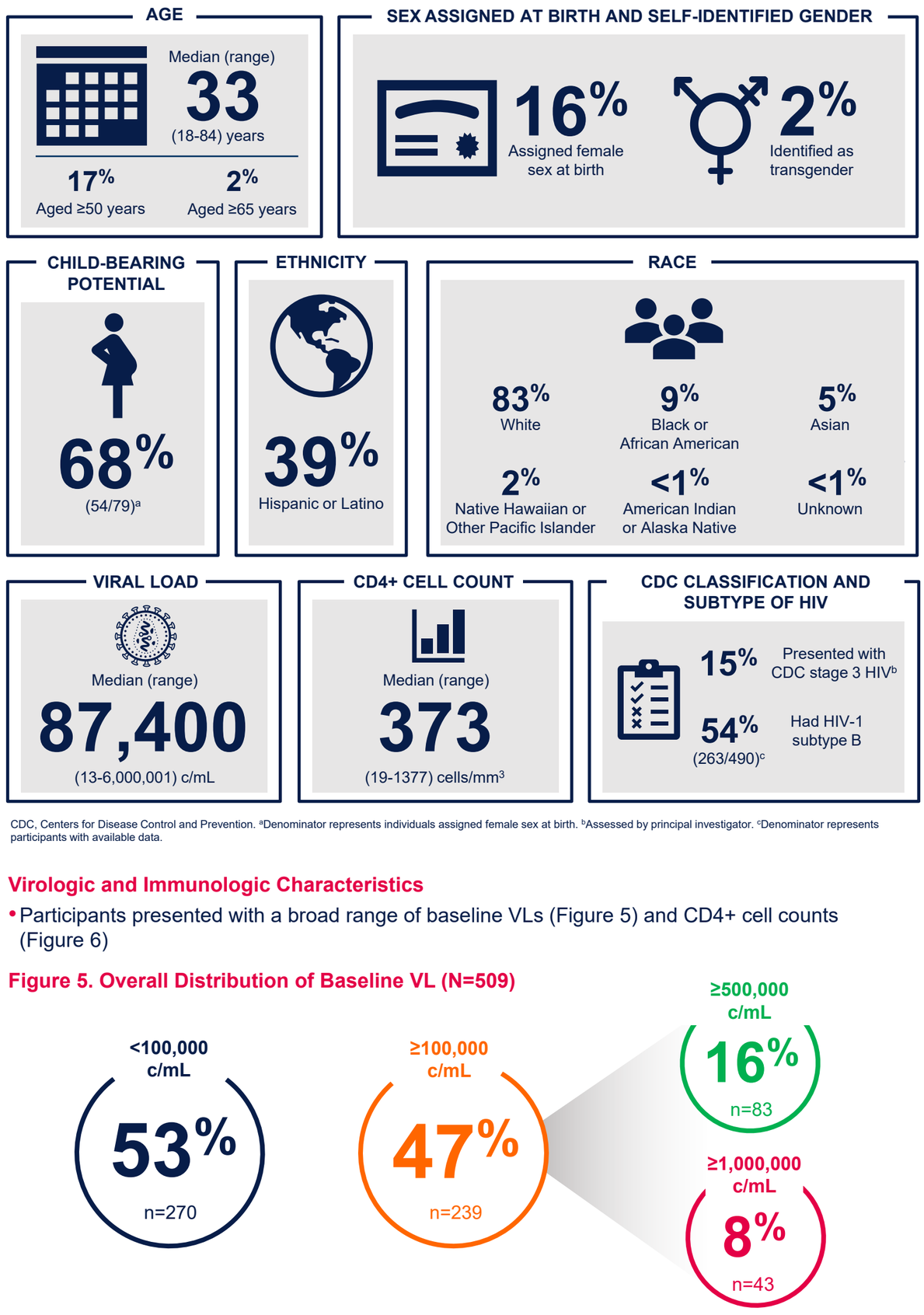


HBcAb, hepatitis B core antibody; HBsAb, hepatitis B surface antibody; HBsAg, hepatitis B surface antigen. [a]HBV status at screening was available for 543 individuals. [b]Nine individuals had an indeterminate HbsAb result and were not classified. [c]Positive for HBsAg. [d]Positive for HBcAb and negative for HBsAg, HBsAb, and HBV DNA. [e]Positive for HBsAb and negative for HBsAg and HBcAb. [f]Positive for HBcAb and HBsAb and negative for HBsAg. [g]Negative for all serologies (HBsAg, HBcAb, HBsAb). [h]Exclusionary RAMs were primarily M184V (n=4); 2 individuals were excluded for other screening criteria, and 2 were discontinued at Week 4 post-initiation despite virologic suppression (n=1 in each treatment group). One participant receiving BIC/FTC/TAF with isolated V75I (a non-polymorphic mutation[10]) detected at low frequency (5%) was virologically suppressed by Week 4 and continued the study.

Participant Demographics

- Baseline characteristics (Figure 4) were comparable between treatment groups

Figure 4. Baseline Characteristics of Overall Randomized Population (N=509)



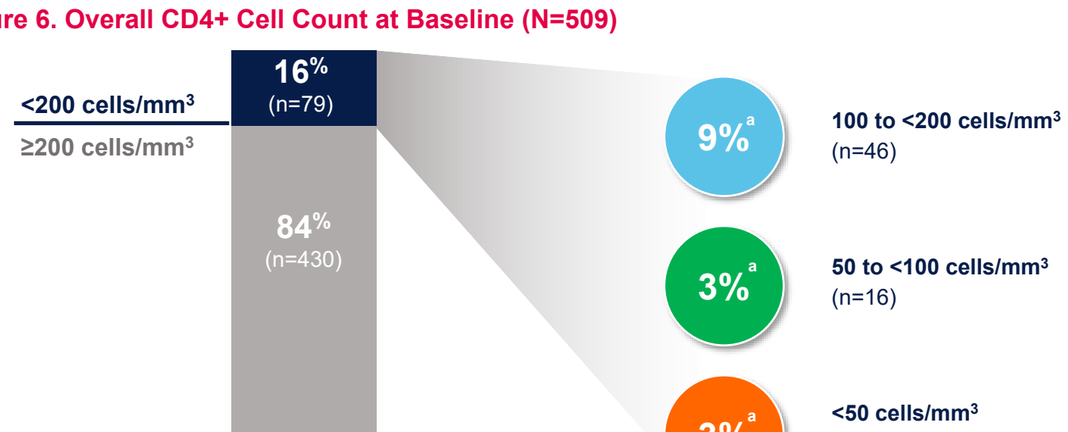
CDC, Centers for Disease Control and Prevention. [a]Denominator represents individuals assigned female sex at birth. [b]Assessed by principal investigator. [c]Denominator represents participants with available data.

Virologic and Immunologic Characteristics

- Participants presented with a broad range of baseline VLs (Figure 5) and CD4+ cell counts (Figure 6)

Figure 5. Overall Distribution of Baseline VL (N=509)

Figure 6. Overall CD4+ Cell Count at Baseline (N=509)



[a]Due to rounding, sum of the percentages may not equal total category value.

Table. Baseline Clinical Characteristics Across Major Clinical Studies Among ART-Naive Populations

Participants, n (%)	VOGUE DTG/3TC (N=254)	VOGUE BIC/FTC/TAF (N=255)	VOLITION[11] DTG/3TC (N=171)	STAT[3] DTG/3TC (N=131)	GEMINI-1/-2; pooled[1,2] DTG/3TC (N=716)[a]	Study 053[12] BIC/FTC/TAF (N=267)	Study 1489[13] BIC/FTC/TAF (N=314)	Study 1490[14] BIC/FTC/TAF (N=320)[b]
HIV-1 RNA ≥100,000 c/mL	126 (50)	113 (44)	65 (38)	51 (39)	140 (20)	101 (38)	53 (17)	54 (17)
HIV-1 RNA ≥500,000 c/mL	45 (18)	38 (15)	15 (9)	19 (15)	13 (2)[c]	28 (10)	—	12 (4)
CD4+ cell count <200 cells/mm^3	40 (16)	39 (15)	27 (16)	37 (28)	63 (9)	38 (14)	36 (11)	44 (14)

[a]DTG 50 mg + 3TC 300 mg used in the GEMINI-1/-2 studies. [b]Study 1490 reported HIV-1 RNA categories of >100,000 and >400,000 c/mL. [c]Although participants with screening HIV-1 RNA ≥500,000 c/mL were excluded from the study, 2% of participants had HIV-1 RNA ≥500,000 c/mL at the baseline visit (which was after the screening visit).

Conclusions

- VOGUE enrolled a broad and clinically relevant population of individuals naive to ART across multiple countries, including 47% with baseline VL ≥100,000 c/mL and 16% with CD4+ cell count <200 cells/mm^3
  - Overall, VOGUE included a greater proportion of participants with high and very high baseline VL and low CD4+ cell count than several major DTG/3TC and BIC/FTC/TAF clinical trials, as shown in the Table
- Active HBV and exclusionary RAMs were uncommon (≤1%) in screening samples
- Efficacy and safety results from the Week 48 analysis are presented separately (scan QR code for full presentation)

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. Cahn et al. *Lancet*. 2019;393:143-155. **2.** Cahn et al. *AIDS*. 2022;36:39-48. **3.** Rolle et al. *AIDS*. 2021;35:1957-1965. **4.** Rolle et al. *Open Forum Infect Dis*. 2025;12:ofaf135. **5.** Cordova et al. *Lancet HIV*. 2025;12:e95-e104. **6.** Figueroa et al. *Clin Infect Dis*. 2026;82:122-131. **7.** Fraysse et al. *Infect Dis Ther*. 2025;14:357-383. **8.** Schneider et al. *Infect Dis Ther*. 2024;13:891-906. **9.** Benson et al. *Infect Dis Ther*. 2024;13:875-889. **10.** Stanford University HIV Drug Resistance Database. https://hivdb.stanford.edu/dr-summary/resistance-notes//#v75i.a. Accessed June 16, 2026. **11.** Cordova et al. AIDS 2025; Kigali, Rwanda. Poster WEPEB033. **12.** Rockstroh et al. *Lancet HIV*. 2026;13:e440-e451. **13.** Gallant et al. *Lancet*. 2017;390:2063-2072. **14.** Sax et al. *Lancet*. 2017;390:2073-2082.

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