# Comparable Week 48 Virologic Outcomes by Adherence Category With DTG/3TC and BIC/FTC/TAF in Adults Initiating ART: Results From VOGUE

P193

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## Key Takeaways

- **In VOGUE, the first randomized, head-to-head trial of DTG/3TC vs BIC/FTC/TAF as first-line ART, 98% of participants achieved ≥90% adherence through Week 48**
- **Week 48 virologic suppression was high and comparable across treatment groups (DTG/3TC vs BIC/FTC/TAF) and adherence categories (≥90% vs <90%); no treatment-emergent resistance was observed**
- **Treatment satisfaction remained high through Week 48 across treatment groups and adherence categories**

## Plain Language Summary


- The VOGUE study compared a 2-drug treatment (dolutegravir/lamivudine) with a 3-drug treatment (bictegravir/emtricitabine/tenofovir alafenamide) in adults starting HIV treatment
- Almost all participants took at least 90% of their doses. After 48 weeks, a similarly high proportion of participants had undetectable HIV virus with either treatment
- Treatment satisfaction was high, supporting dolutegravir/lamivudine as a treatment option for a wide range of people starting HIV treatment, including those with occasional missed doses

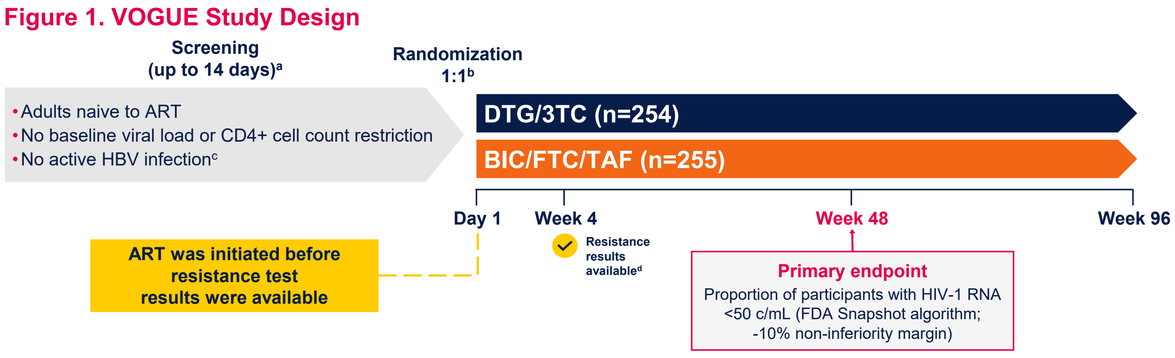

## Introduction

- Clinical trial and real-world evidence have demonstrated that virologic suppression with dolutegravir/lamivudine (DTG/3TC) can be maintained across a range of adherence levels[1,2]
  - Further clinical evidence in a US setting supports the use of DTG/3TC in a test-and-treat paradigm,[3] where antiretroviral therapy (ART) starts at diagnosis, before adherence patterns are established
- Data directly comparing the impact of adherence on virologic outcomes with contemporary first-line, integrase strand transfer inhibitor–based regimens, including 2- and 3-drug regimens, are limited
- In VOGUE, the first randomized, head-to-head trial comparing DTG/3TC with bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) as first-line ART in adults with HIV-1 using a test-and-treat approach, DTG/3TC demonstrated non-inferior efficacy at Week 48, with no treatment-emergent resistance observed[4]
- Here, we evaluated the impact of adherence (≥90% vs <90%) on Week 48 virologic suppression and treatment satisfaction in VOGUE

## Methods

- VOGUE (NCT05979311) is an ongoing phase 3b, randomized, open-label, non-inferiority study comparing DTG/3TC vs BIC/FTC/TAF as first-line ART in adults with HIV-1 (Figure 1)
- Adherence, an exploratory endpoint, was categorized as ≥90% or <90% and calculated from participant-reported missed doses through Week 48
- Virologic suppression (HIV-1 RNA <50 c/mL; Snapshot algorithm) at Week 48 was assessed by adherence category
- Confirmed virologic withdrawal (CVW) was defined as 2 consecutive plasma HIV-1 RNA measurements meeting protocol-defined criteria for either virologic non-response or virologic rebound (HIV-1 RNA ≥200 c/mL)
- Treatment satisfaction was evaluated using the 10-item HIV Treatment Satisfaction Questionnaire, status version (HIVTSQs) at Weeks 4 (baseline for treatment satisfaction), 12, 24, and 48
- HIVTSQs total score is computed based on items 1-10, which are summed to produce a total score ranging from 0-60

### Figure 1. VOGUE Study Design



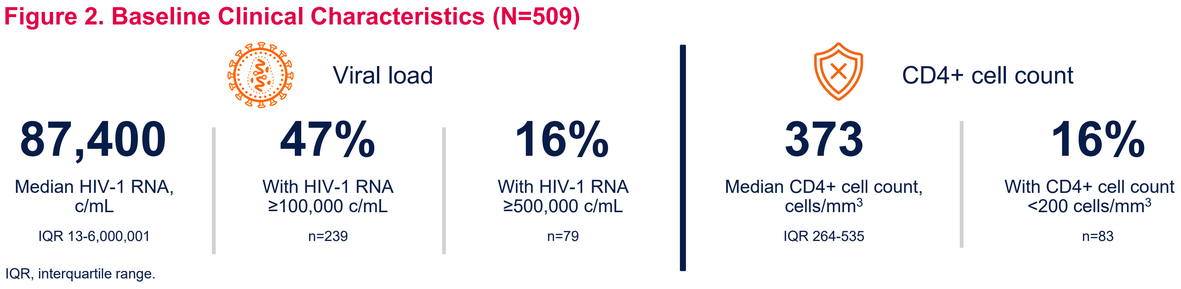

FDA, US Food and Drug Administration; HBcAb, hepatitis B core antibody; HBV, hepatitis B virus. [a]Extenuating situations could delay the Day 1 visit beyond 14 screening days. [b]Stratified by plasma HIV-1 RNA (<100,000 vs ≥100,000 c/mL) and CD4+ cell count (<200 vs ≥200 cells/mm$^3$) at screening. [c]Participants 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. [d]Participants with major resistance-associated mutations to integrase strand transfer inhibitors, 3TC, FTC, or TAF were required to discontinue study treatment.

## Results

### Baseline Demographics and Characteristics

- VOGUE enrolled a clinically diverse population without baseline viral load or CD4+ cell count restrictions (Figure 2)
- Of 509 participants, median (range) age was 33 (18-84) years, 16% (n=79) were female sex at birth, and 39% (n=197) were Hispanic or Latino; demographics and baseline characteristics were comparable between treatment groups

### Figure 2. Baseline Clinical Characteristics (N=509)

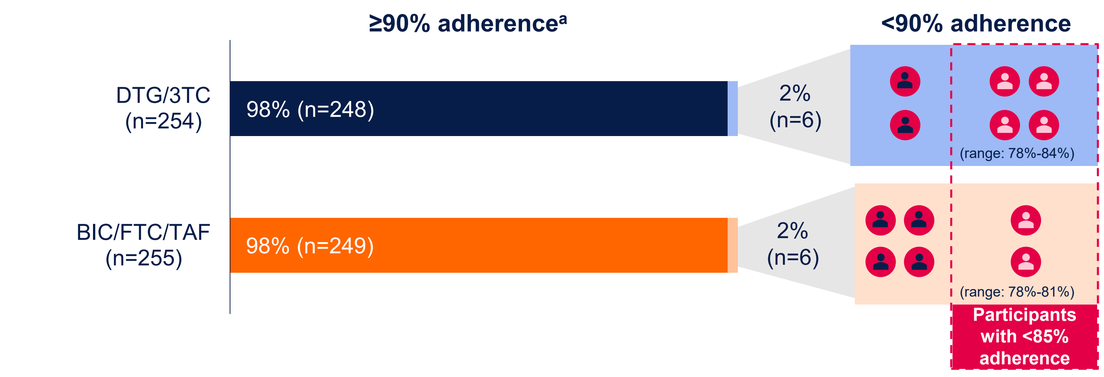



IQR, interquartile range.

### Adherence

- Adherence was high and similar between treatment groups, with 98% of participants in both groups achieving ≥90% adherence across all visits (Figure 3)
- 12 participants had <90% adherence (n=6 per group); of these, 4 participants receiving DTG/3TC and 2 receiving BIC/FTC/TAF had <85% adherence

### Figure 3. High Adherence Rates Across Treatment Groups Through Week 48

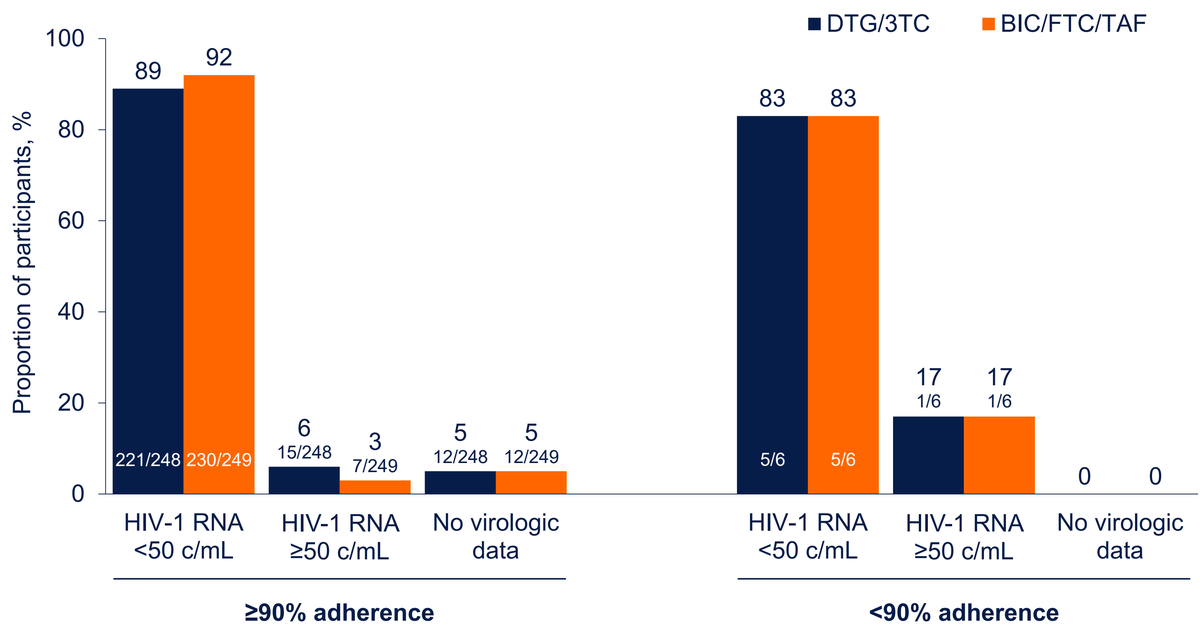



[a]100% adherence achieved by 313 participants (DTG/3TC, n=164; BIC/FTC/TAF, n=149); 95% to <100% adherence achieved by 160 participants (DTG/3TC, n=73; BIC/FTC/TAF, n=87); and 90% to <95% adherence achieved by 24 participants (DTG/3TC, n=11; BIC/FTC/TAF, n=13).

### Virologic Outcomes by Adherence Category

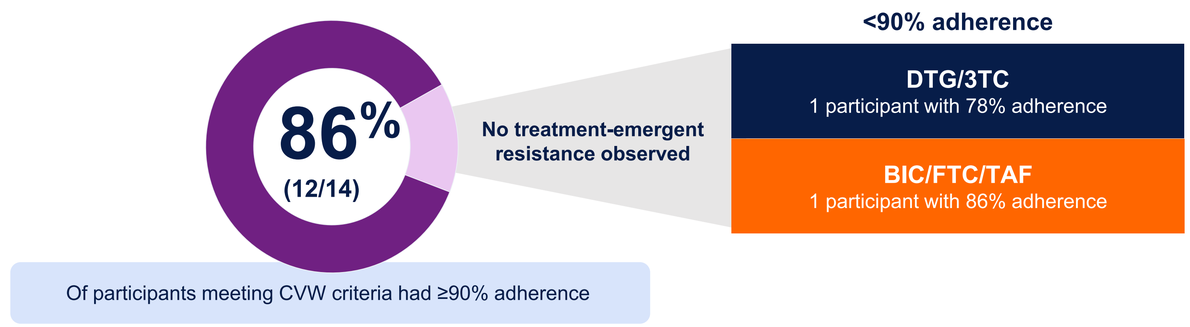
- At Week 48, virologic suppression rates were high across adherence categories, with comparable rates between DTG/3TC and BIC/FTC/TAF (Figure 4)

### Figure 4. High Virologic Suppression (HIV-1 RNA <50 c/mL; Snapshot Algorithm) Across Adherence Categories at Week 48




- Overall, 14 participants (DTG/3TC, n=7; BIC/FTC/TAF, n=7) met CVW criteria by Week 48 (Figure 5)
- No treatment-emergent resistance was observed for 6/14 participants (DTG/3TC, n=2; BIC/FTC/TAF, n=4) with CVW, including 2 participants with <90% adherence
  - For the remaining 8 participants, resistance testing failed due to the viral load of testing samples being below the assay cutoff

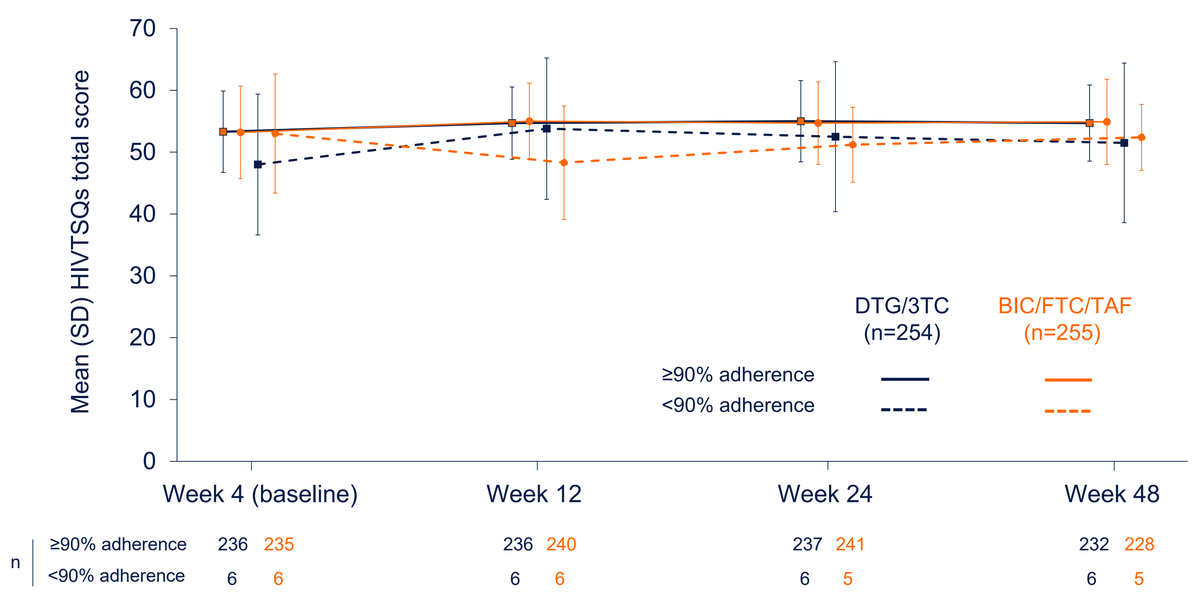
### Figure 5. Most Participants Meeting CVW Criteria Had ≥90% Adherence




### Treatment Satisfaction

- Treatment satisfaction was high across both adherence groups at Week 4 and remained stable through Week 48, regardless of regimen (Figure 6)

### Figure 6. High Treatment Satisfaction Across Adherence Categories Maintained Through Week 48[a]




[a]HIVTSQs total score is computed to produce a score between 0-60, with higher scores representing greater treatment satisfaction. Positive changes indicate increased treatment satisfaction.

## Conclusions

- In VOGUE, adherence was high and similar between DTG/3TC and BIC/FTC/TAF through 48 weeks
- Virologic suppression remained high across treatment groups and adherence categories, with no treatment-emergent resistance observed
- High treatment satisfaction was sustained
- Findings support DTG/3TC in adults initiating ART in a test-and-treat approach and are consistent with previous data showing efficacy in clinical settings where adherence may be compromised[1,2]

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**References: 1.** Ait-Khaled et al. *HIV Res Clin Pract*. 2021;23:9-14. **2.** Sax et al. *AIDS Res Ther*. 2025;22:90. **3.** Rolle et al. *AIDS*. 2021;35:1957-1965. **4.** Ghosn et al. *Open Forum Infect Dis*. 2026;13:ofag471.



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