VOGUE: Consistent Efficacy of DTG/3TC Versus BIC/FTC/TAF Across Clinically Relevant Subgroups in Adults Initiating ART

P051

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Key Takeaways

- **VOGUE is the first randomized, head-to-head study comparing the 2-drug regimen DTG/3TC with the 3-drug regimen BIC/FTC/TAF as first-line ART using a test-and-treat approach with no baseline VL or CD4+ cell count restrictions**
- **At Week 48, DTG/3TC showed efficacy comparable to BIC/FTC/TAF across evaluated subgroups, including those with high baseline VLs or low CD4+ cell counts**
- **Time to virologic suppression and safety outcomes were similar between regimens across subgroups, reinforcing DTG/3TC as a first-line 2-drug treatment option**

Plain Language Summary

- VOGUE is the first clinical trial that compared the 2-drug HIV regimen dolutegravir/lamivudine with the 3-drug regimen bictegravir/emtricitabine/tenofovir alafenamide in people starting HIV treatment for the first time
  - Participants could be enrolled regardless of the amount of virus in their blood or the strength of their immune system at the start of treatment
- The 2-drug regimen controlled HIV as well as, and worked as quickly as, the 3-drug regimen in the different groups of participants evaluated in the study
- The overall safety findings were generally similar between treatments
- These results support dolutegravir/lamivudine as an effective 2-drug treatment option for people beginning HIV treatment, including across the groups evaluated in this analysis

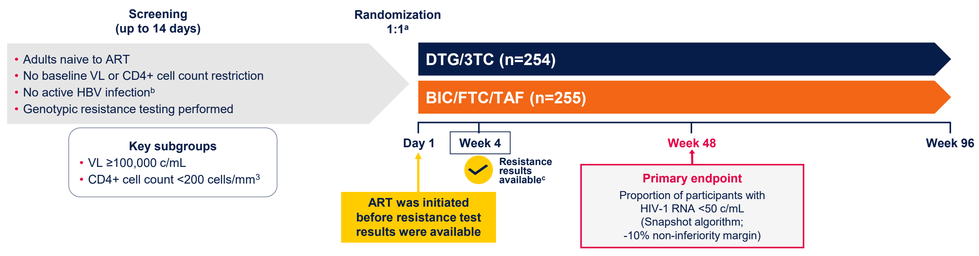
Introduction

- Dolutegravir/Lamivudine (DTG/3TC) is a 2-drug regimen supported by over 10 years of evidence showing consistent effectiveness in diverse clinical trials and real-world settings for both people naive to antiretroviral therapy (ART) and those with virologic suppression[1-7]
- VOGUE is the first randomized study demonstrating virologic non-inferiority of DTG/3TC vs bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) at Week 48 in a broad population without baseline viral load (VL) or CD4+ cell count restrictions using a test-and-treat approach[8]
- Outcomes in advanced disease are an important consideration for initial treatment and warrant further characterization
- This analysis evaluated Week 48 efficacy and safety across baseline demographic and disease-severity subgroups

Methods

- VOGUE (NCT05979311) is an ongoing, phase 3b, randomized, open-label, non-inferiority study evaluating DTG/3TC vs BIC/FTC/TAF through 96 weeks in adults with HIV-1 naive to ART (Figure 1)[8]
- The primary endpoint, HIV-1 RNA <50 c/mL (Snapshot algorithm) at Week 48, was analyzed across prespecified demographic and disease-severity subgroups (the HIV-1 RNA <200 c/mL threshold was also assessed); treatment differences were estimated using Bayesian shrinkage (exploratory) to reduce variability from small subgroup sizes[8]
- For key prespecified subgroups (baseline VL ≥100,000 c/mL and CD4+ cell count <200 cells/mm^3), time to HIV-1 RNA <50 c/mL was assessed using Kaplan-Meier methods, with hazard ratios from a Cox proportional-hazards model adjusted for randomization strata; changes from baseline in HIV-1 RNA (log_{10} c/mL) were assessed post hoc; and adverse events were summarized descriptively[8]

Figure 1. VOGUE: Phase 3b, Randomized, Open-Label, Non-Inferiority Study



HBV, hepatitis B virus. [a]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. [b]Participants with immunity to HBV, including those with isolated hepatitis B core antibody positivity without detectable HBV DNA, were not excluded. [c]Participants with major resistance-associated mutations to integrase strand transfer inhibitors, 3TC, FTC, or TAF were required to discontinue study treatment.

Results

Baseline Characteristics

- Overall, 509 participants were randomized to DTG/3TC (n=254) or BIC/FTC/TAF (n=255)[8]; 47% (239/509) had baseline VL ≥100,000 c/mL and 16% (79/509) had baseline CD4+ cell count <200 cell/mm^3
  - 13% (67/509) of participants had both baseline VL ≥100,000 c/mL and CD4+ cell count <200 cells/mm^3
- Baseline characteristics were generally balanced across baseline VL and CD4+ cell count subgroups (Table 1)

Table 1. VOGUE Enrolled a Population With High VL and Low CD4+ Cell Count at Baseline

	Baseline VL ≥100,000 c/mL		Baseline CD4+ cell count <200 cells/mm^3	
Parameter	**DTG/3TC (n=126)**	**BIC/FTC/TAF (n=113)**	**DTG/3TC (n=40)**	**BIC/FTC/TAF (n=39)**
Age, median (range), y	35 (18-72)	34 (18-84)	38 (23-64)	36 (22-73)
Sex at birth, female, n (%)	13 (10)	13 (12)	5 (12)	6 (15)
Race (self-reported), n (%)				
White	111 (88)	94 (83)	33 (82)	34 (87)
Black or African American	7 (6)	10 (9)	3 (8)	3 (8)
Asian	6 (5)	6 (5)	3 (8)	2 (5)
Other race	2 (2)[a]	3 (3)[b]	1 (2)[c]	0
Ethnicity (self-reported), Hispanic or Latine, n (%)	45 (36)	37 (33)	16 (40)	12 (31)
Plasma HIV-1 RNA, median (range), log_{10} c/mL	5.57 (5.00-6.56)	5.49 (5.01-6.79)	5.52 (4.24-6.50)	5.61 (3.99-6.79)
≥100,000 c/mL, n (%)	126 (100)	113 (100)	31 (78)	36 (92)
≥500,000 c/mL, n (%)	45 (36)	38 (34)	17 (42)	14 (36)
CD4+ cell count, median (range), cells/mm^3	331 (19-826)	304 (19-858)	119 (19-190)	107 (19-193)
<200 cells/mm^3, n (%)	31 (25)	36 (32)	40 (100)	39 (100)

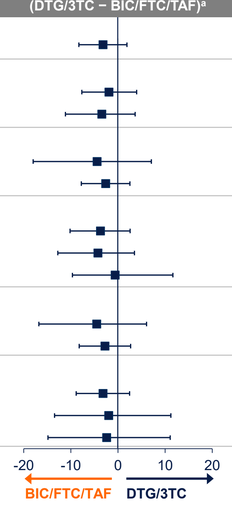
[a]Includes American Indian or Alaska Native (n=1) and unknown (n=1). [b]Includes American Indian or Alaska Native (n=1), Native Hawaiian or Other Pacific Islander (n=1), and unknown (n=1). [c]Includes American Indian or Alaska Native (n=1).

Efficacy by Subgroup

- Rates of virologic suppression (HIV-1 RNA <50 c/mL) were comparable between DTG/3TC and BIC/FTC/TAF across demographic and disease-severity subgroups, including those with baseline VL ≥100,000 c/mL or CD4+ cell count <200 cells/mm^3 (Figure 2)
  - Results were consistent when using the HIV-1 RNA <200 c/mL threshold (Figure 3)
- No treatment-emergent resistance was identified in the study through Week 48[8]

Figure 2. Comparable Virologic Suppression (HIV-1 RNA <50 c/mL) Across Clinically Relevant Subgroups With DTG/3TC and BIC/FTC/TAF at Week 48 (Snapshot Algorithm)

Subgroup	Participants, n (%)	Adjusted treatment difference (DTG/3TC − BIC/FTC/TAF)[a] % (95% CI)	HIV-1 RNA <50 c/mL, % (n/N) DTG/3TC	BIC/FTC/TAF
Overall	**509**	**-3 (-8, 2)**	**89% (226/254)**	**92% (235/255)**
Baseline VL, c/mL		% (95% CrI)		
<100,000	270 (53)	-2 (-8, 4)	**93%** (119/128)	**94%** (134/142)
≥100,000	239 (47)	-3 (-11, 4)	**85%** (107/126)	**89%** (101/113)
Baseline CD4+ cell count, cells/mm^3				
<200	79 (16)	-4 (-18, 7)	**78%** (31/40)	**85%** (33/39)
≥200	430 (84)	-3 (-8, 3)	**91%** (195/214)	**94%** (202/216)
Age, y				
18 to <35	278 (55)	-4 (-10, 3)	**88%** (123/139)	**93%** (129/139)
35 to <50	145 (28)	-4 (-13, 3)	**88%** (67/76)	**94%** (65/69)
≥50	86 (17)	-1 (-10, 12)	**92%** (36/39)	**87%** (41/47)
Sex at birth				
Female	79 (16)	-5 (-17, 6)	**85%** (35/41)	**92%** (35/38)
Male	430 (84)	-3 (-8, 3)	**90%** (191/213)	**92%** (200/217)
Race				
White	423 (83)	-3 (-9, 2)	**88%** (186/211)	**92%** (194/212)
Black/African American	44 (9)	-2 (-13, 11)	**92%** (22/24)	**90%** (18/20)
Asian	26 (5)	-2 (-15, 11)	**100%** (14/14)	**100%** (12/12)



Efficacy analyses used the Abbott RealTi*m*e HIV-1 assay; the Roche cobas 6800 HIV-1 assay was used for participant management and assessment of change in HIV-1 RNA. CrI, credible interval. [a]For the overall population, adjusted treatment difference and 95% CI were estimated using a Cochran-Mantel-Haenszel method across baseline VL and CD4+ cell count strata. For subgroups, treatment differences and 95% CrIs were analyzed using Bayesian shrinkage estimation.

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Figure 3. Consistent Virologic Suppression Results Across Clinically Relevant Subgroups With DTG/3TC and BIC/FTC/TAF at Week 48 When Using HIV-1 RNA <200 c/mL Threshold (Snapshot Algorithm)

Subgroup	Participants, n (%)	Adjusted treatment difference (DTG/3TC − BIC/FTC/TAF)[a] % (95% CI)	HIV-1 RNA <200 c/mL, % (n/N) DTG/3TC	BIC/FTC/TAF
Overall	**509**	**1 (-4, 5)**	**94% (239/254)**	**93% (238/255)**
Baseline VL, c/mL		% (95% CrI)		
<100,000	270 (53)	0 (-6, 5)	**94%** (120/128)	**95%** (135/142)
≥100,000	239 (47)	2 (-4, 9)	**94%** (119/126)	**91%** (103/113)
Baseline CD4+ cell count, cells/mm^3				
<200	79 (16)	4 (-7, 17)	**93%** (37/40)	**85%** (33/39)
≥200	430 (84)	0 (-5, 4)	**94%** (202/214)	**95%** (205/216)
Age, y				
18 to <35	278 (55)	0 (-5, 6)	**94%** (130/139)	**94%** (130/139)
35 to <50	145 (28)	-1 (-8, 6)	**93%** (71/76)	**96%** (66/69)
≥50	86 (17)	3 (-5, 14)	**97%** (38/39)	**89%** (42/47)
Sex at birth				
Female	79 (16)	-1 (-14, 9)	**88%** (36/41)	**92%** (35/38)
Male	430 (84)	1 (-3, 6)	**95%** (203/213)	**94%** (203/217)
Race				
White	423 (83)	1 (-4, 6)	**94%** (198/211)	**93%** (197/212)
Black/African American	44 (9)	2 (-10, 15)	**96%** (23/24)	**90%** (18/20)
Asian	26 (5)	1 (-13, 13)	**100%** (14/14)	**100%** (12/12)



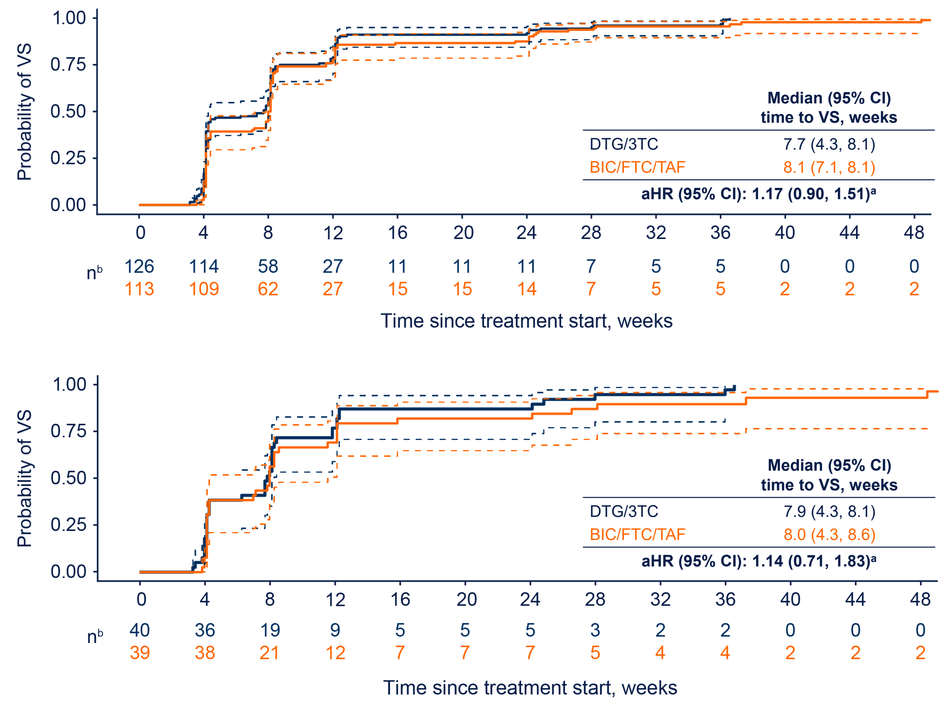
CrI, credible interval. [a]For the overall population, adjusted treatment difference and 95% CI were estimated using a Cochran-Mantel-Haenszel method across baseline VL and CD4+ cell count strata. For subgroups, treatment differences and 95% CrIs were analyzed using Bayesian shrinkage estimation.

Time to Virologic Suppression by Key Prespecified Subgroups

- Median time to virologic suppression in the overall population was rapid and similar between treatment groups at 4.1 weeks (adjusted hazard ratio [95% CI]: 1.23 [1.03, 1.47])[8]; median time to virologic suppression was approximately 8 weeks in participants with baseline VL ≥100,000 c/mL or CD4+ cell count <200 cells/mm^3 (Figure 4)

Figure 4. Time to Virologic Suppression Was Rapid and Comparable Between Treatment Groups for (A) Baseline VL ≥100,000 c/mL and (B) Baseline CD4+ Cell Count <200 cells/mm^3

A



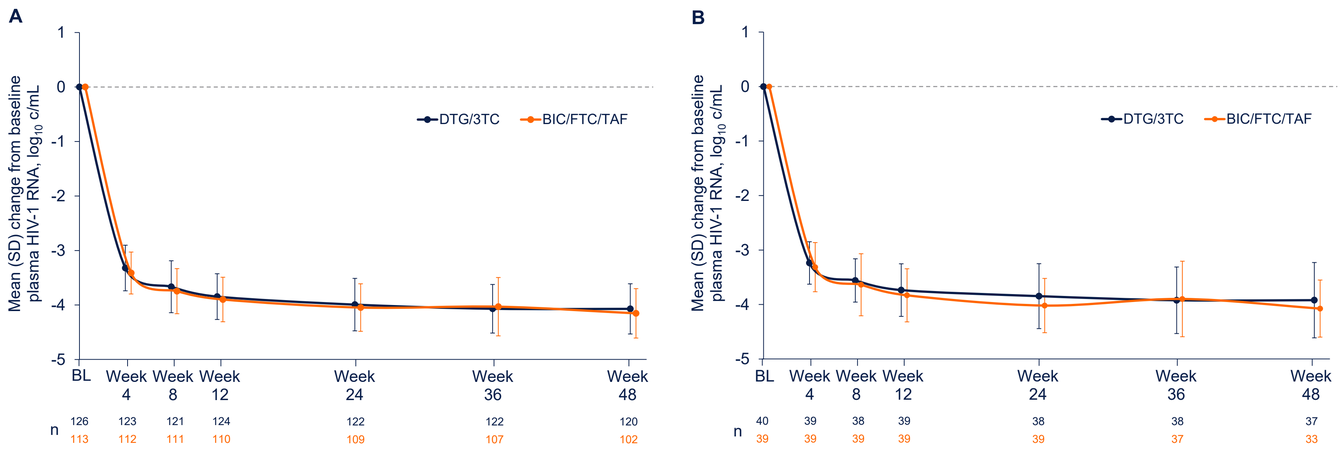
B

aHR, adjusted hazard ratio; VS, virologic suppression. [a]Estimated using a Cox proportional-hazards model, with treatment as a covariate and controlled for baseline VL and CD4+ cell count randomization strata. [b]Number of participants at risk and remaining on study at the start of each study visit window. Participants who withdrew from the study without achieving VS were censored.

Changes in HIV-1 RNA by Key Prespecified Subgroups

- In the baseline VL ≥100,000 c/mL subgroup, mean baseline HIV-1 RNA was similar for DTG/3TC and BIC/FTC/TAF (5.58 vs 5.61 log_{10} c/mL, respectively); mean HIV-1 RNA levels in both groups rapidly declined by Week 8 (mean change, -3.67 vs -3.75 log_{10} c/mL; Figure 5A)
- The CD4+ cell count <200 cells/mm^3 subgroup showed a similar pattern, with comparable mean baseline HIV-1 RNA values between DTG/3TC and BIC/FTC/TAF (5.50 vs 5.59 log_{10} c/mL, respectively) and steep and comparable declines by Week 8 (mean change, -3.56 vs -3.64 log_{10} c/mL; Figure 5B)

Figure 5. Changes in HIV-1 RNA Occurred by Week 8 and Were Comparable Between Treatment Groups for (A) Baseline VL ≥100,000 c/mL and (B) Baseline CD4+ Cell Count <200 cells/mm^3



BL, baseline.

Safety by Key Prespecified Subgroups

- Safety outcomes were generally similar between treatment groups overall and across key baseline VL and CD4+ cell count subgroups (Table 2)

Table 2. Safety Outcomes Were Generally Similar Across Evaluated Subgroups

	Overall		Baseline VL ≥100,000 c/mL		Baseline CD4+ cell count <200 cells/mm^3	
Parameter, n (%)	**DTG/3TC (n=254)**	**BIC/FTC/TAF (n=255)**	**DTG/3TC (n=126)**	**BIC/FTC/TAF (n=113)**	**DTG/3TC (n=40)**	**BIC/FTC/TAF (n=39)**
Any AE	224 (88)	237 (93)	113 (90)	106 (94)	35 (88)	37 (95)
Drug-related AE	44 (17)	49 (19)	21 (17)	24 (21)	8 (20)	9 (23)
SAE	23 (9)	20 (8)	11 (9)	12 (11)	5 (12)	5 (13)
AE leading to discontinuation	3 (1)	3 (1)	1 (<1)	2 (2)	2 (5)	2 (5)
Drug-related AE leading to discontinuation	0	2 (<1)[a]	0	1 (<1)[b]	0	1 (3)[b]

AE, adverse event; SAE, serious AE. [a]Alopecia and increased weight (n=1 each). [b]Alopecia (n=1, in a participant with both baseline VL ≥100,000 c/mL and CD4+ cell count <200 cells/mm^3).

Conclusions

- In people with baseline VL ≥100,000 c/mL or CD4+ cell count <200 cells/mm^3, proportions with Week 48 suppression and time to suppression were similar between DTG/3TC and BIC/FTC/TAF. Virologic outcomes were similar across other demographic subgroups with no resistance through Week 48
- These data support DTG/3TC as a first-line option in a test-and-treat setting, including for people presenting with high VL or low CD4+ cell count
- For additional evidence across the baseline VL continuum, including very high VL populations, see Cahn et al, Poster 688

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