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In VOGUE: DTG/3TC Demonstrates Non-Inferior Efficacy to BIC/FTC/TAF as First-Line Treatment

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Disclosures

- Jade Ghosn has received honoraria from Gilead Sciences, GSK, MSD, and ViiV Healthcare outside of this work

Summary

What is your main question?

- Is the 2-drug regimen DTG/3TC non-inferior to the 3-drug regimen BIC/FTC/TAF as first-line treatment in the phase 3b, randomized VOGUE trial?

What did you find?

- DTG/3TC demonstrated non-inferior efficacy to BIC/FTC/TAF at Week 48, with no treatment-emergent resistance
- Virologic suppression was rapid in both treatment groups

Why is it important?

- VOGUE provides the first randomized, head-to-head evidence comparing DTG/3TC with BIC/FTC/TAF in a broad population initiating HIV-1 treatment in a test-and-treat approach

BIC, bictegravir; DTG, dolutegravir; FTC, emtricitabine; TAF, tenofovir alafenamide; 3TC, lamivudine.

Introduction

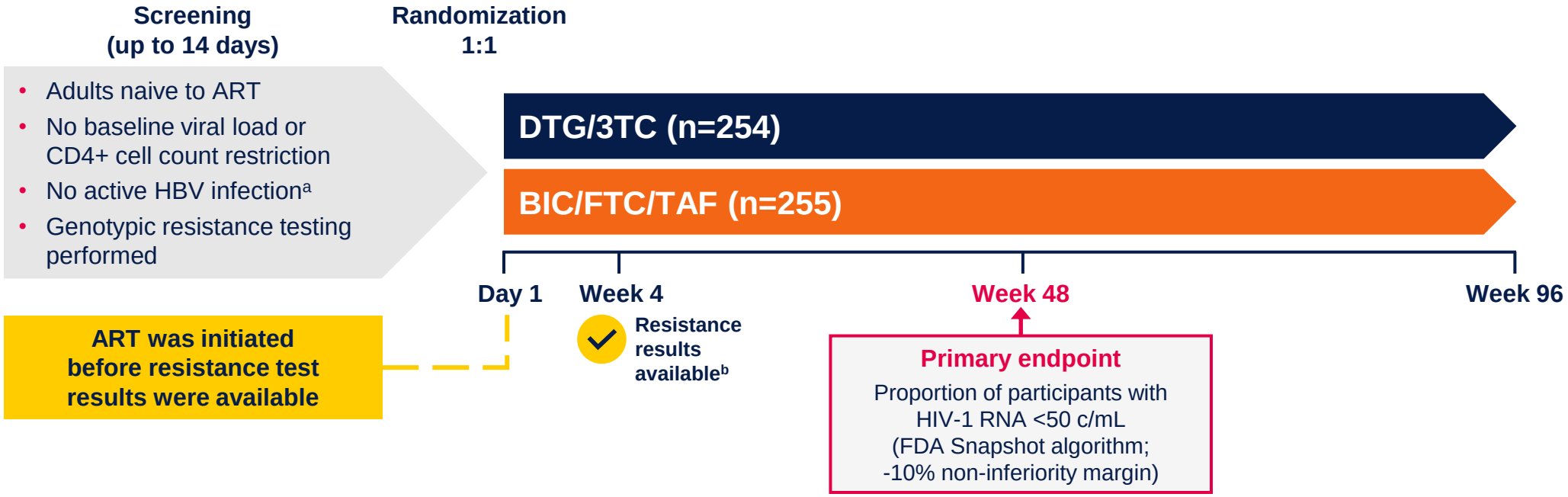
- DTG/3TC is a guideline-recommended 2-drug regimen with extensive clinical trial and real-world experience[1-7]
- In individuals initiating ART, DTG/3TC has consistently demonstrated high and similar efficacy to 3-drug regimens in randomized trials[4,8-11]
- No phase 3 study has directly compared the 2-drug regimen DTG/3TC with the 3-drug regimen BIC/FTC/TAF as first-line treatment
- **VOGUE is the first randomized, head-to-head comparison of DTG/3TC vs BIC/FTC/TAF in a broad population initiating HIV-1 treatment in a test-and-treat approach**

ART, antiretroviral therapy.

1. Gandhi et al. *JAMA*. 2025;333:609-628. **2.** Panel on Antiretroviral Guidelines for Adults and Adolescents. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed June 18, 2026. **3.** European AIDS Clinical Society. https://www.eacsociety.org/guidelines/eacs-guidelines. Accessed June 18, 2026. **4.** Cahn et al. *AIDS*. 2022;36:39-48. **5.** Osiyemi et al. *Clin Infect Dis*. 2022;75:975-986. **6.** Llibre et al. *Clin Infect Dis*. 2023;76:720-729. **7.** Fraysse et al. *Infect Dis Ther*. 2025;14:357-383. **8.** Cahn et al. *Lancet*. 2019;393:143-155. **9.** Cahn et al. *J Acquir Immune Defic Syndr*. 2022;83:310-318. **10.** Cordova et al. *Lancet HIV*. 2025;12:e95-e104. **11.** Figueroa et al. *Clin Infect Dis*. 2026;82:122-131.

VOGUE Study Design

Phase 3b, randomized, open-label, non-inferiority study (NCT05979311)



- Randomization was stratified by plasma HIV-1 RNA (< vs ≥100,000 c/mL) and CD4+ cell count (< vs ≥200 cells/mm^3)

Countries: Argentina, Belgium, Denmark, France, Germany, Greece, Ireland, Israel, Italy, Japan, Mexico, Poland, Portugal, Spain, Sweden, Switzerland, and United Kingdom.

ART, antiretroviral therapy; FDA, US Food and Drug Administration; HBV, hepatitis B virus; INSTI, integrase strand transfer inhibitor.

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

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VOGUE Study Population

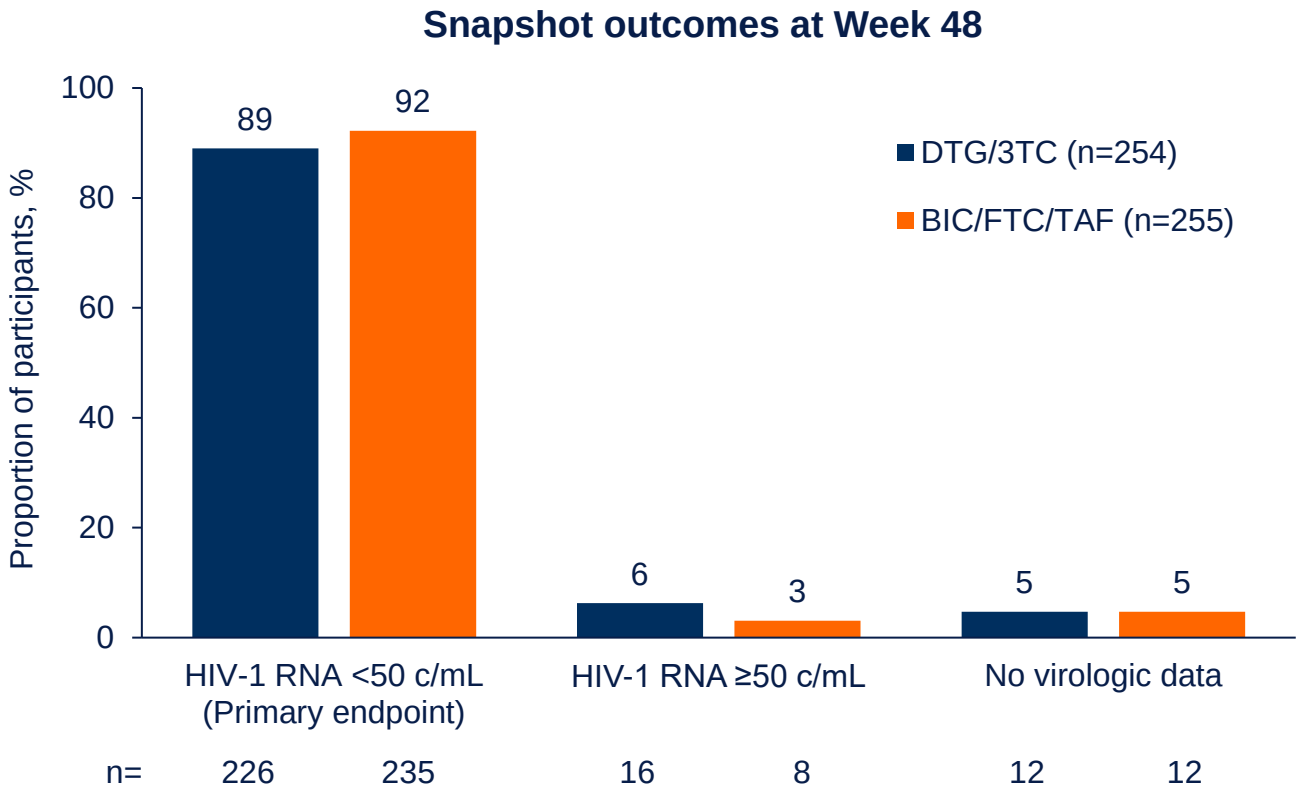
See Poster WEPEB094 for additional data

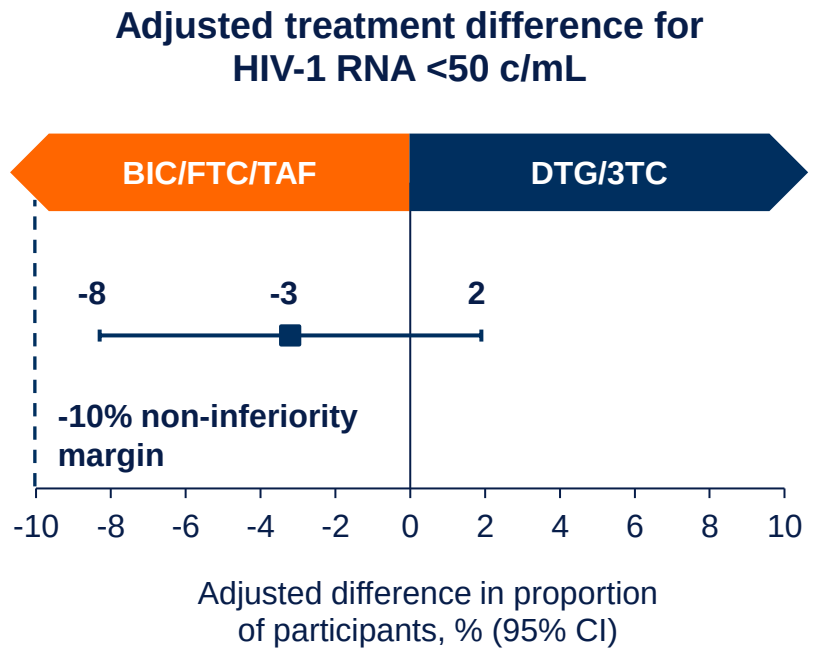
Parameter	DTG/3TC (n=254)	BIC/FTC/TAF (n=255)	Total (N=509)
Age, median (range), y	33 (18-73)	33 (18-84)	33 (18-84)
Sex assigned at birth, female, n (%)	41 (16)	38 (15)	79 (16)
Race (self-reported), n (%)			
White	211 (83)	212 (83)	423 (83)
Black or African American	24 (9)	20 (8)	44 (9)
Asian	14 (6)	12 (5)	26 (5)
Other[a]	5 (2)	11 (4)	16 (3)
Ethnicity (self-reported), Hispanic or Latino, n (%)	100 (39)	97 (38)	197 (39)
Plasma HIV-1 RNA, median (IQR), log_{10} c/mL	4.98 (4.40-5.56)	4.92 (4.39-5.45)	4.94 (4.40-5.46)
≥100,000 c/mL, n (%)	126 (50)	113 (44)	239 (47)
≥500,000 c/mL, n (%)	45 (18)	38 (15)	83 (16)
CD4+ cell count, median (IQR), cells/mm^3	375 (267-548)	372 (257-529)	373 (264-535)
<200 cells/mm^3, n (%)	40 (16)	39 (15)	79 (16)
Time from screening to treatment initiation, median (IQR), d	10 (8-14)	10 (8-14)	10 (8-14)

- 0.4% (2/548) of screened individuals were excluded due to active hepatitis B virus infection
- 1 participant in each treatment group with baseline M184V achieved HIV-1 RNA <50 c/mL at Week 4 and discontinued study treatment per protocol

[a]American Indian or Alaska Native (DTG/3TC, n=1; BIC/FTC/TAF, n=4), Native Hawaiian or other Pacific Islander (DTG/3TC, n=3; BIC/FTC/TAF, n=5), or unknown race (DTG/3TC, n=1; BIC/FTC/TAF, n=2).

DTG/3TC Demonstrates High and Non-Inferior Efficacy to BIC/FTC/TAF at Week 48



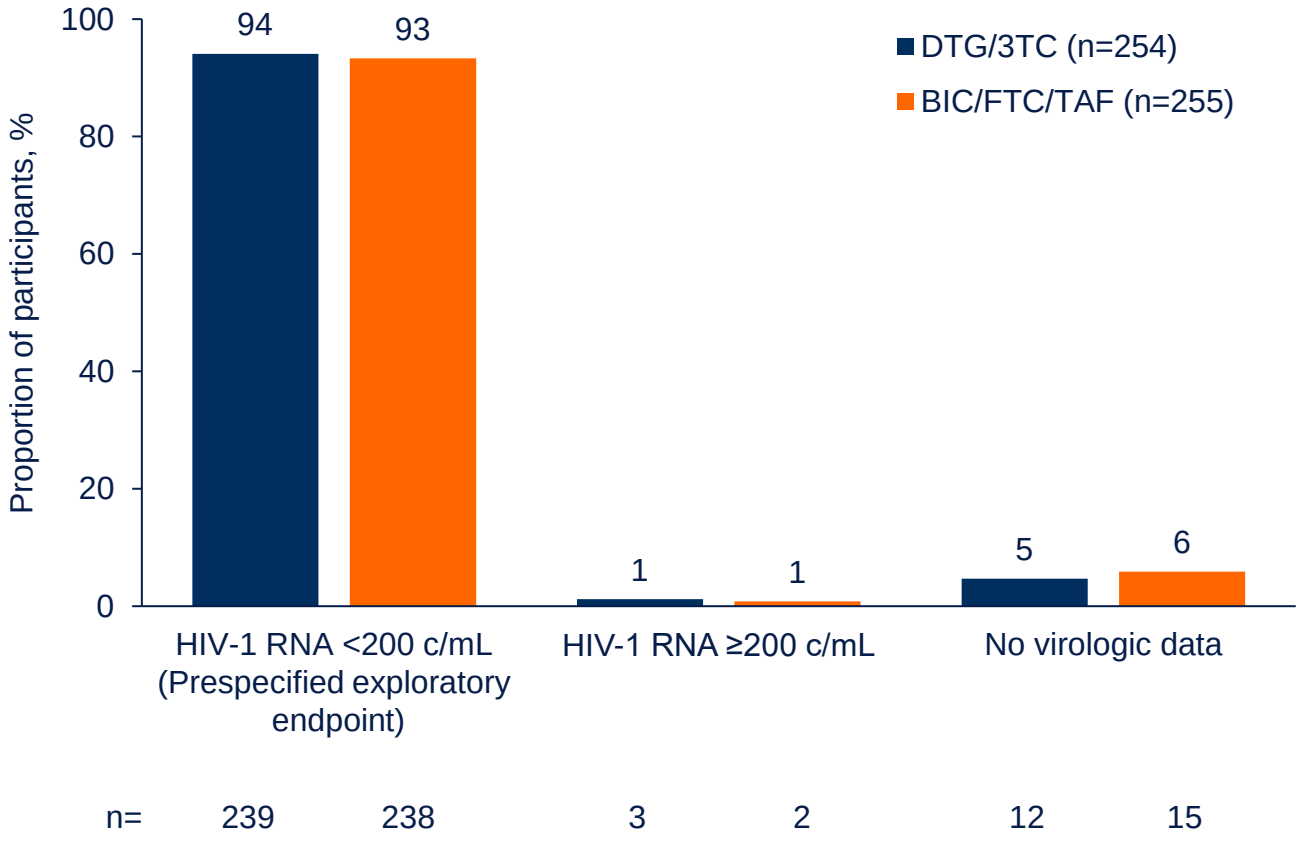


- Most instances of Snapshot HIV-1 RNA ≥50 c/mL were viral load blips <200 c/mL after prior suppression to <50 c/mL, and participants continued on study[a]

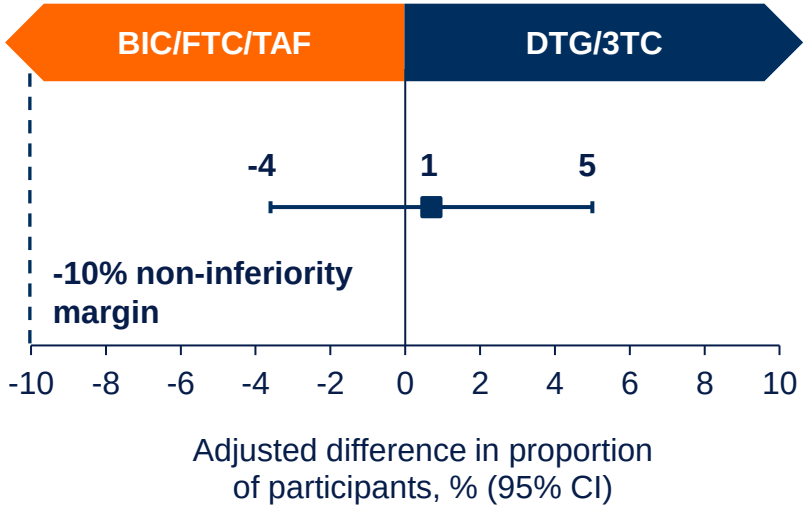
[a]DTG/3TC: Of 16 participants with Snapshot HIV-1 RNA ≥50 c/mL at Week 48, 9/12 with available data at the next visit resuppressed to <50 c/mL. BIC/FTC/TAF: Of 8 participants with Snapshot HIV-1 RNA ≥50 c/mL at Week 48, 2/3 with available data at the next visit resuppressed to <50 c/mL.

DTG/3TC Meets the Non-Inferior Efficacy Threshold Versus BIC/FTC/TAF For Achieving HIV-1 RNA 200 c/mL

Snapshot outcomes at Week 48 using a 200 c/mL threshold



Adjusted treatment difference for HIV-1 RNA <200 c/mL



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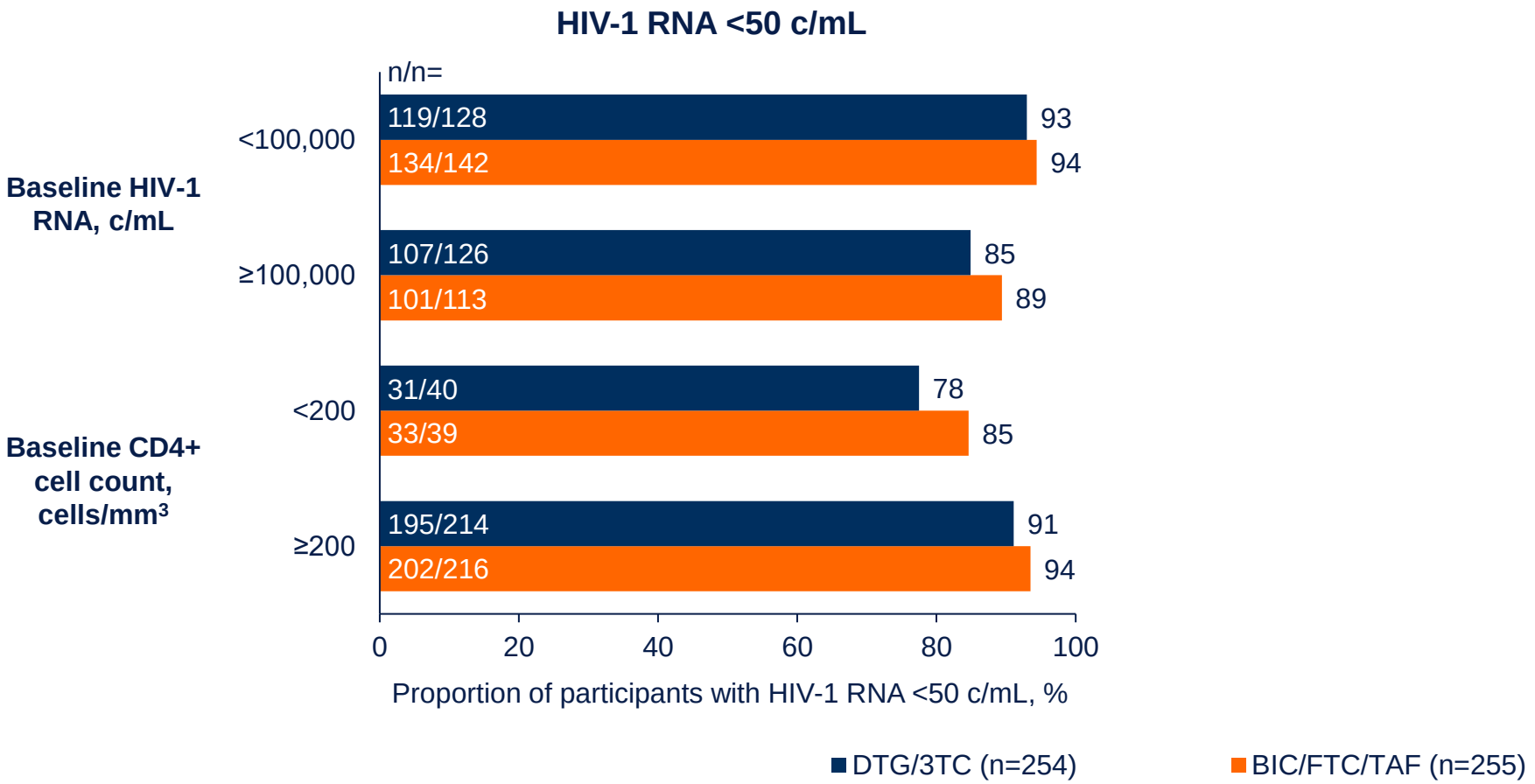
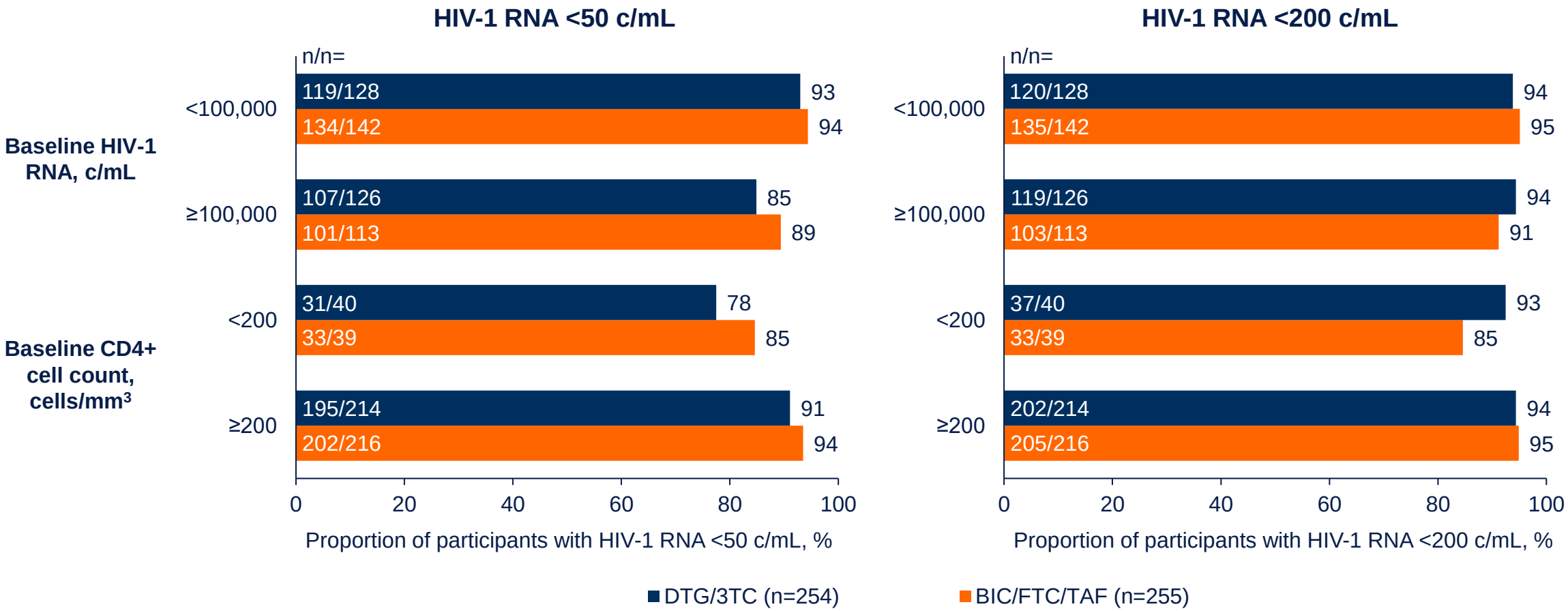
High Virologic Suppression Observed Across Randomization Strata



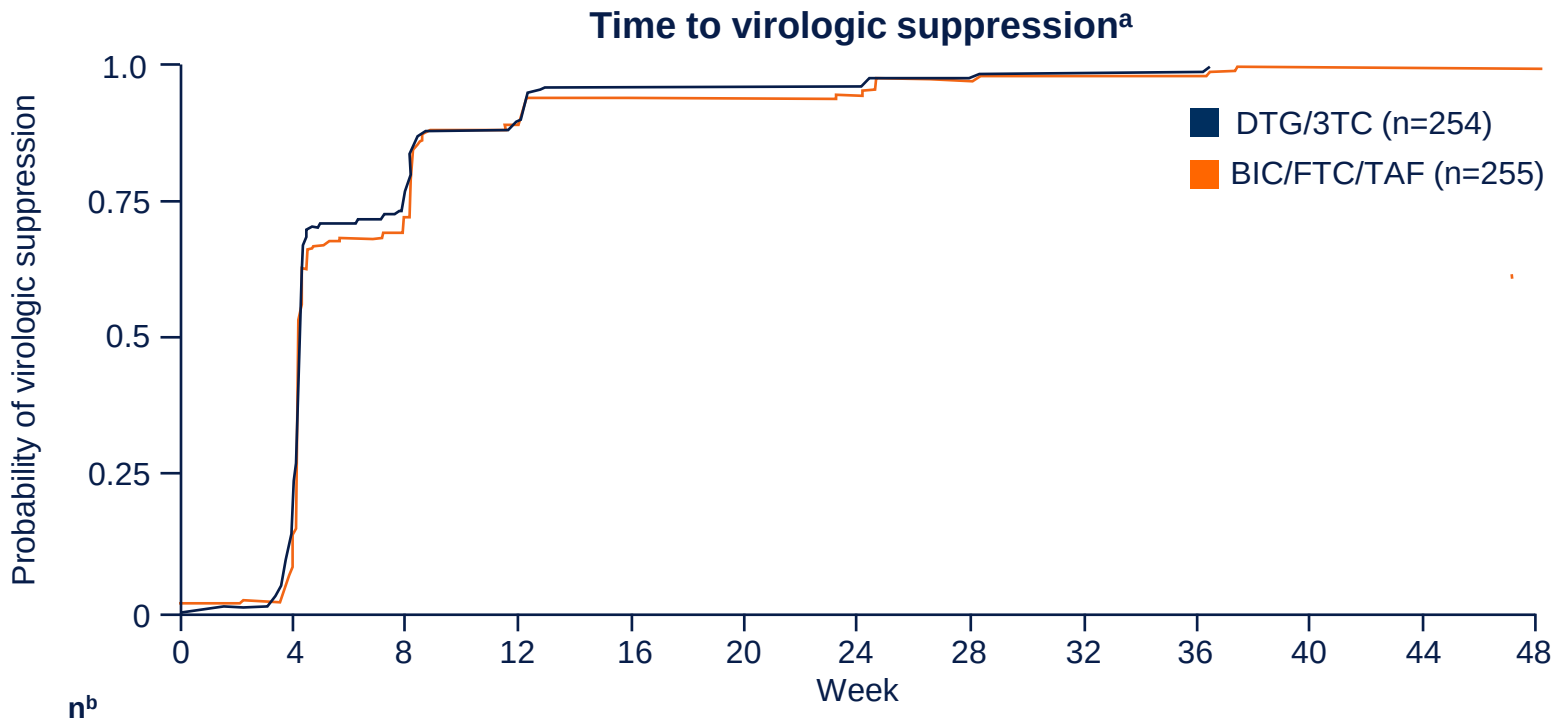
Efficacy was consistent across clinically important baseline subgroups

High Virologic Suppression Observed Across Randomization Strata



Efficacy was consistent across clinically important baseline subgroups

Virologic Suppression Was Rapid in Both Treatment Groups



n[b]													
DTG/3TC	254	221	63	27	11	11	11	7	5	5	0	0	0
BIC/FTC/TAF	255	232	72	29	16	16	15	8	6	6	2	2	2

- Participants receiving DTG/3TC had a 23% higher hazard of achieving virologic suppression than those receiving BIC/FTC/TAF (adjusted hazard ratio, 1.23 [95% CI, 1.03, 1.47]; *P*=0.0357)[c]
- Median (95% CI) time to virologic suppression was 4.1 (4.1, 4.1) weeks for DTG/3TC and 4.1 (4.1, 4.3) weeks for BIC/FTC/TAF

[a]First viral load <50 c/mL. [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 virologic suppression were censored. [c]Estimated using a Cox proportional-hazards model, with treatment as a covariate and controlled for randomization strata.

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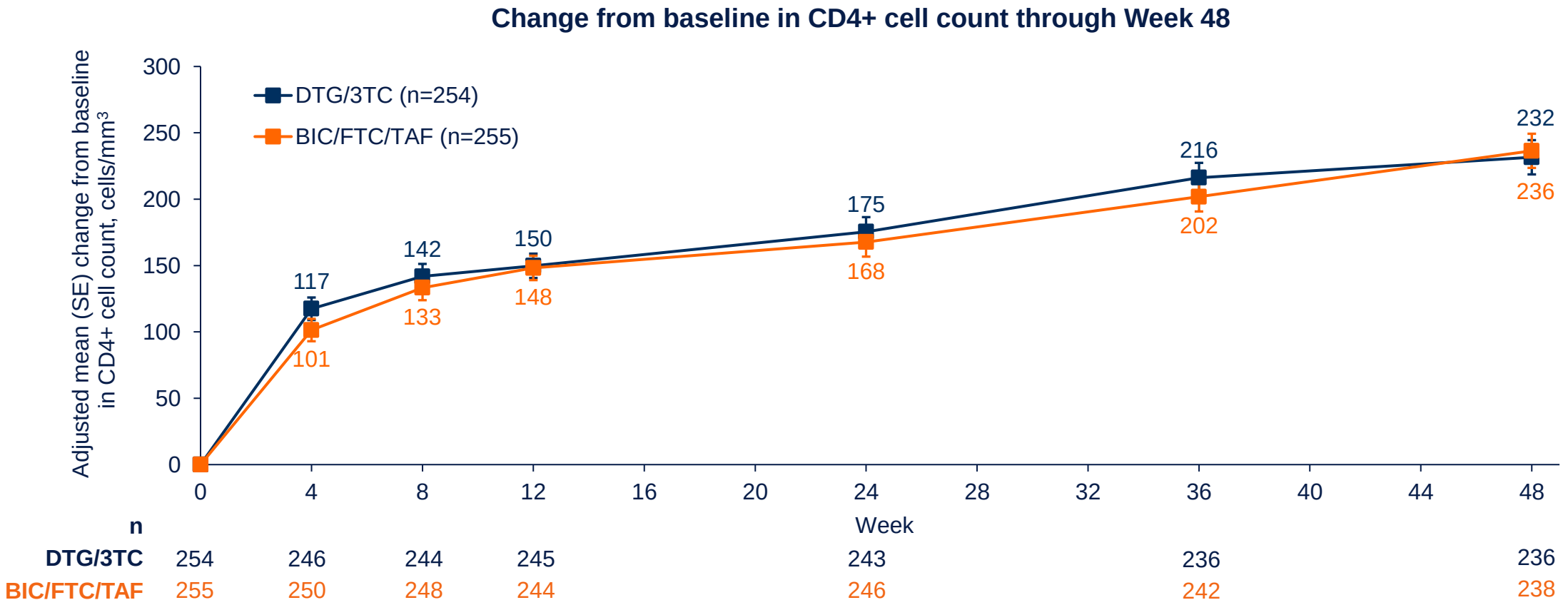
CD4+ Cell Count Recovery Was Similar Between Treatment Groups Through Week 48



Baseline median (IQR) CD4+ cell counts were 375 (267-548) cells/mm³ for DTG/3TC and 372 (257-529) cells/mm³ for BIC/FTC/TAF.

Adjusted mean change from baseline was calculated using a mixed model for repeated measures, adjusting for treatment, visit, baseline CD4+ cell count, baseline plasma HIV-1 RNA (< vs ≥100,000 c/mL), treatment-by-visit interaction, and baseline CD4+ cell count-by-visit interaction, with visit as a repeated factor.

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No Treatment-Emergent Resistance Was Identified Through Week 48

- CVW was defined as 2 consecutive plasma HIV-1 RNA measurements meeting protocol-defined criteria for either virologic non-response or virologic rebound (≥200 c/mL)

Outcome, n (%)	DTG/3TC (n=254)	BIC/FTC/TAF (n=255)
CVW by Week 48	**7 (3)**	**7 (3)**
Virologic non-response	0	1
Virologic rebound	7	6
Treatment-emergent resistance[a,b]	**0**	**0**

CVW, confirmed virologic withdrawal; INSTI, integrase strand transfer inhibitor; NRTI, nucleoside reverse transcriptase inhibitor.

[a]Baseline and virologic withdrawal samples (including available suspected virologic withdrawal and/or confirmatory samples meeting HIV-1 RNA thresholds ≥200 c/mL) were analyzed for resistance using next-generation sequencing by Cerba Laboratory (3% detection threshold) for participants in the European Union or Monogram Biosciences (10% detection threshold) for participants outside of the European Union.

[b]Among 14 participants meeting CVW criteria, resistance data were obtained for 6 individuals (DTG/3TC, n=2; BIC/FTC/TAF, n=4), and no treatment-emergent resistance to INSTIs or NRTIs was identified. For the remaining 8 participants (DTG/3TC, n=5; BIC/FTC/TAF, n=3), resistance testing failed due to viral load of samples being below the assay cutoff.

Safety Profiles Were Comparable Between Treatment Groups

- No drug-related SAEs or fatal SAEs occurred in the study
- No new HBV infections or reactivations were observed
- Mean change in weight from baseline to Week 48 was +3.6 kg for DTG/3TC and +4.0 kg for BIC/FTC/TAF

Parameter, n (%)	DTG/3TC (n=254)	BIC/FTC/TAF (n=255)
Any AE	224 (88)	237 (93)
Grade 3-4 AE[a]	26 (10)	27 (11)
Drug-related AE	44 (17)	49 (19)
Grade 3-4 drug-related AE[a]	1 (<1)	1 (<1)
SAE	23 (9)	20 (8)
AE leading to discontinuation	3 (1)	3 (1)
Drug-related AE leading to discontinuation	0	2 (<1)[b]

AE, adverse event; HBV, hepatitis B virus; SAE, serious adverse event.

[a]There were no grade 5 AEs. [b]Alopecia and increased weight (n=1 each).

Overall incidence of AEs was similar, and AEs leading to discontinuation were uncommon in both treatment groups. No drug-related discontinuations occurred with DTG/3TC.

Conclusions

- **DTG/3TC demonstrated non-inferior efficacy vs BIC/FTC/TAF at Week 48 in a broad population initiating treatment**
  - **No baseline viral load or CD4+ cell count restrictions**
  - **No treatment-emergent resistance**
- VOGUE provides the first randomized, head-to-head evidence comparing 2-drug DTG/3TC with 3-drug BIC/FTC/TAF as initial ART
- Virologic suppression was rapid in both treatment groups
- Safety outcomes and immunologic recovery were comparable between treatment groups through Week 48
- These findings reinforce DTG/3TC as an effective, first-line, 2-drug option for a broad population initiating ART when used in a test-and-treat approach

ART, antiretroviral therapy.

VOGUE: Publication in *Open Forum Infectious Diseases*

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Open Forum Infectious Diseases

MAJOR ARTICLE

VOGUE: Non-Inferior Efficacy of Dolutegravir/Lamivudine Versus Bictegravir/Emtricitabine/Tenofovir Alafenamide in Adults With HIV-1 Naive to Treatment

Jade Ghosn,[1,2] Federico Pulido,[3] Gustavo D. Lopardo,[4] Anita Olczak,[5] Diego Ripamonti,[6] Charlotte Martin,[7] Orlando Paredes Ceballos,[8] Hartmut Stocker,[9,10] Maria Josefina Mendez Vazquez,[11] Hiroyuki Gatanaga,[12] Simeon Metallidis,[13] Daniel Elbirt,[14] Gary Whitlock,[15] José Ignacio Mateo González,[16] Perry Mohammed,[17] Kehui Wang,[18] Richard Grove,[19] Ruolan Wang,[20] Adelaide Jewell,[17] Kenneth Sutton,[20] Emilie Elliot,[21] Riya Moodley,[17] Rebecca Borsi,[20] Bryn Jones,[17] Michelle Kisare,[17*] Piotr Budnik,[17] Jean van Wyk,[17] for the VOGUE study group

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