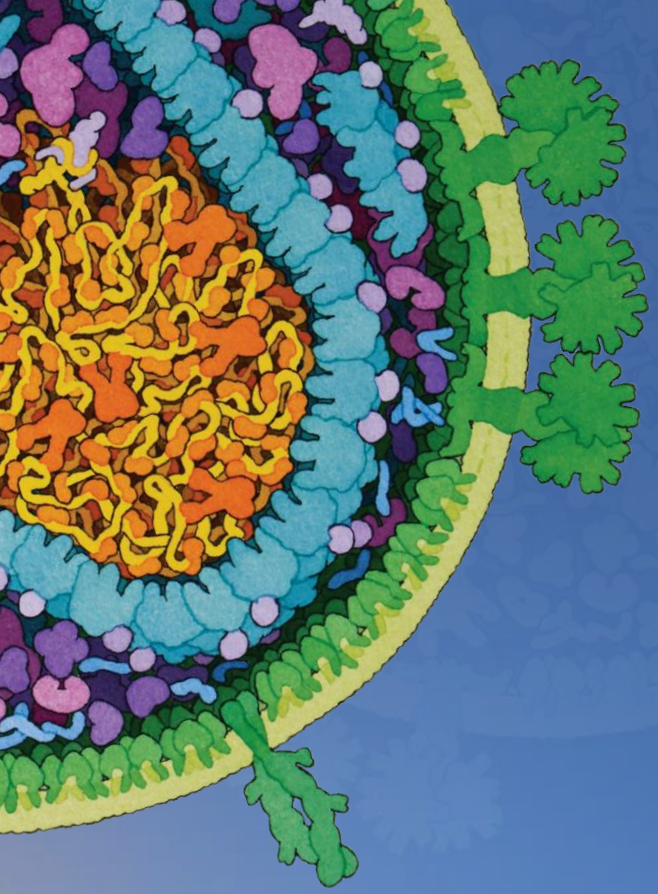

SCIENCE SPOTLIGHT™

SWITCHING TO DTG/3TC FDC IS NON-INFERIOR TO TAF-BASED REGIMENS FOR 96 WEEKS: TANGO SUBGROUP ANALYSES

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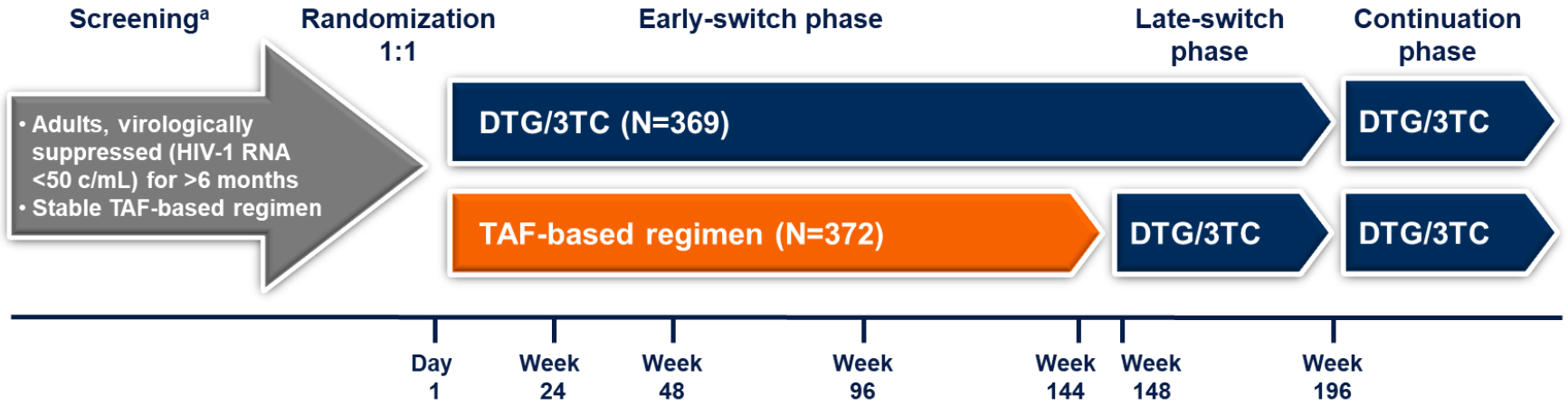
Background

- TANGO (NCT03446573) is an ongoing phase III, non-inferiority trial evaluating efficacy and safety of a switch to DTG/3TC fixed-dose combination in adults with HIV-1 infection who are virologically suppressed on a 3- or 4-drug TAF-based regimen[1]
- In the Week 48 primary analysis and Week 96 analysis of TANGO, switching to DTG/3TC FDC was non-inferior to remaining on a TAF-based regimen in ART-experienced, virologically suppressed adults[2,3]
- Here we present rates of virologic suppression (Snapshot) through Week 96 by demographic characteristics, baseline third agent class, and disease characteristics

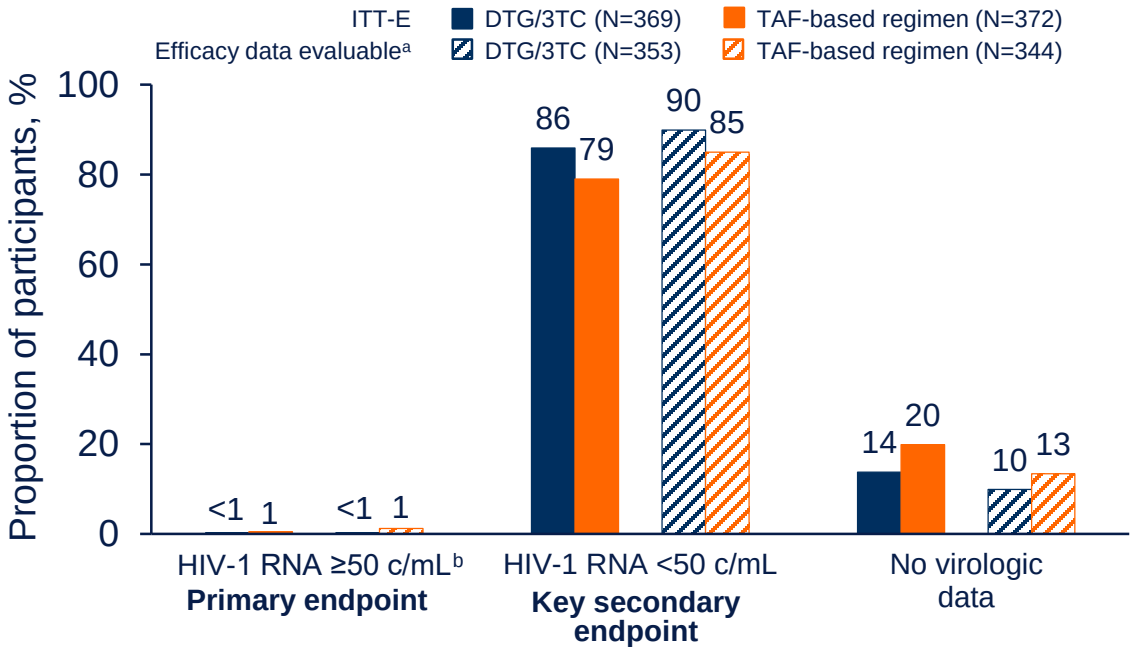


[a]Participants were eligible if they had ≥2 documented HIV-1 RNA measurements <50 c/mL, no HBV infection or need for HCV therapy, no prior VF and no documented NRTI or INSTI resistance, and TAF/FTC + PI or INSTI or NNRTI as initial regimen.

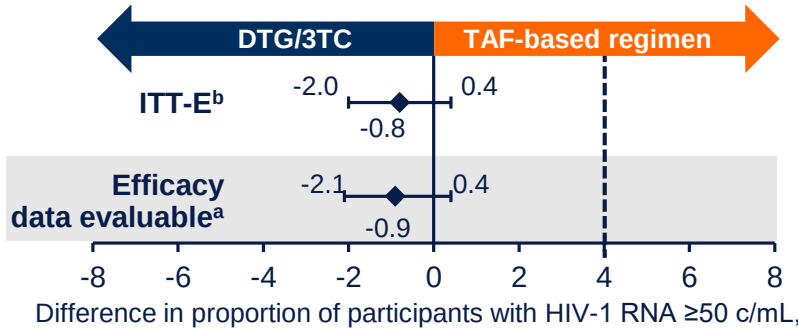
1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03446573. Accessed January 26, 2021. **2.** van Wyk et al. *Clin Infect Dis*. 2020;71:1920-1929. **3.** van Wyk et al. HIV Glasgow 2020; Virtual. Slides O441.

DTG/3TC Is Non-inferior to TAF-Based Regimen at Week 96

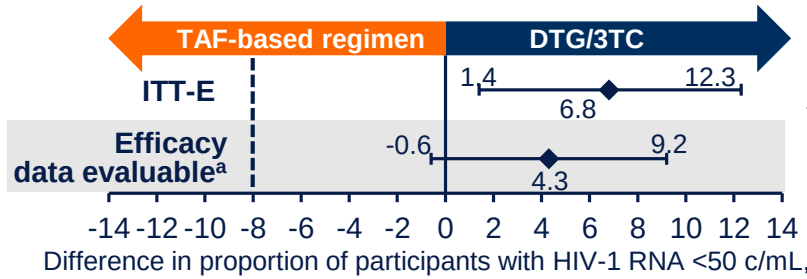
Virologic outcomes (Snapshot analysis)



Adjusted treatment difference (95% CI)[c]



HIV-1 RNA ≥50 c/mL
DTG/3TC is non-inferior to TAF-based regimen at Week 96 based on a 4% non-inferiority margin

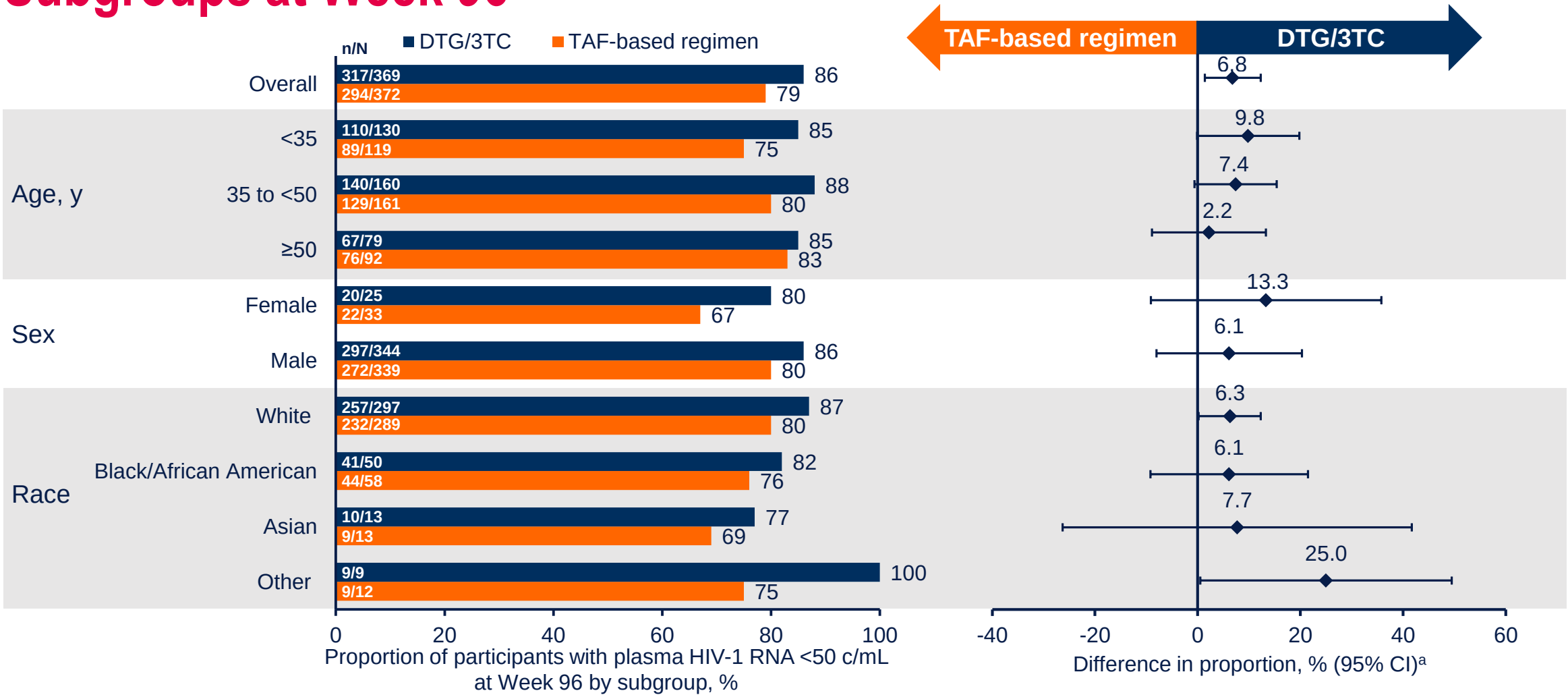


HIV-1 RNA <50 c/mL
DTG/3TC is non-inferior to TAF-based regimen at Week 96 based on a −8% non-inferiority margin

- Superiority was demonstrated in the **per-protocol analysis**: 0/348 participants in the DTG/3TC group and 4/351 in the TAF-based regimen group had HIV-1 RNA ≥50 c/mL at Week 96 (adjusted difference, −1.1%; 95% CI, −2.3% to −0.0%; *P*=0.044)
- In the DTG/3TC group, there were no cases of confirmed virologic withdrawal through Week 96 and 3 cases in the TAF-based regimen group; no resistance mutations were observed

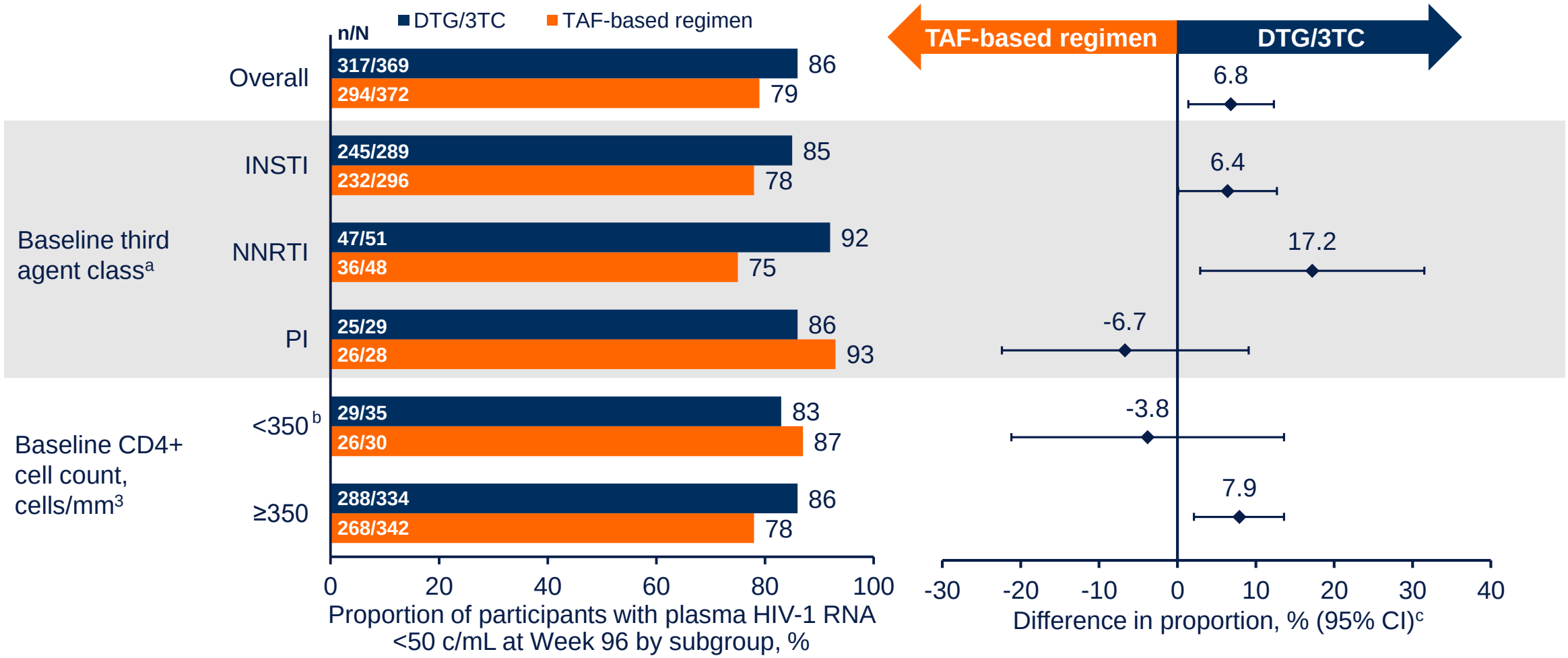
[a]Sensitivity analysis excluding 16 and 28 participants in the DTG/3TC and TAF-based regimen groups, respectively, because of no Week 96 HIV-1 RNA data due to effects of the COVID-19 pandemic. [b]Primary endpoint (Snapshot virologic non-response, ITT-E). [c]Based on Cochran-Mantel-Haenszel stratified analysis (DTG/3TC − TAF-based regimen) adjusting for baseline third agent class.

HIV-1 RNA <50 c/mL Was Comparable Across Demographics Subgroups at Week 96



[a]Adjusted difference for overall population (DTG/3TC − TAF-based regimen) and 95% CI are based on a stratified analysis (adjusting for baseline third agent class) using Cochran-Mantel-Haenszel weights (meeting non-inferiority based on −8% margin). Unadjusted difference for subgroups calculated by proportion on DTG/3TC − proportion on TAF-based regimen.

HIV-1 RNA <50 c/mL Was Comparable Across Baseline Characteristics Subgroups at Week 96



[a]The study population was stratified by baseline third agent class (PI, INSTI, or NNRTI). [b]Includes 14 participants with baseline CD4+ cell count <200 cells/mm^3: 71% (5/7) in the DTG/3TC group and 100% (7/7) in the TAF-based regimen group. [c]Adjusted difference for overall population (DTG/3TC − TAF-based regimen) and 95% CI are based on a stratified analysis (adjusting for baseline third agent class) using Cochran-Mantel-Haenszel weights (meeting non-inferiority based on −8% margin). Unadjusted difference for subgroups calculated by proportion on DTG/3TC − proportion on TAF-based regimen.

Frequency of All Adverse Events by Subgroup Through Week 96: Safety Population

Variable	Subgroup	DTG/3TC n/N	DTG/3TC %	TAF-based regimen n/N	TAF-based regimen %
Overall	—	324/369	88	325/371	88
Age, y	<35	108/130	83	102/119	86
	35 to <50	143/160	89	142/161	88
	≥50	73/79	92	81/91	89
Sex	Female	23/25	92	28/33	85
	Male	301/344	88	297/338	88
Race	White	264/297	89	259/288	90
	Black or African American	40/50	80	45/58	78
	Asian	12/13	92	11/13	85
	Other	8/9	89	10/12	83
Baseline third agent class	INSTI	250/289	87	255/296	86
	NNRTI	46/51	90	42/47	89
	PI	28/29	97	28/28	100
Baseline CD4+ cell count, cells/mm^3	<350	31/35	89	27/30	90
	≥350	293/334	88	298/341	87

- Rates of adverse events occurring between Weeks 48 and 96 were similar between treatment groups[1]

1. van Wyk et al. HIV Glasgow 2020; Virtual. Slides O441.

Conclusions

- Switching to DTG/3TC FDC was non-inferior to continuing a TAF-based regimen in maintaining virologic suppression in ART-experienced adults with HIV-1 infection through Week 96
- Efficacy by subgroups was consistent with overall Week 96 study results
- Safety by subgroups was consistent with overall Week 96 results and consistent with the DTG and 3TC labels
- These results demonstrate that switching from TAF-based regimens to DTG/3TC FDC is effective and durable for the maintenance of virologic suppression regardless of baseline regimen, or participant or disease characteristics

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