

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

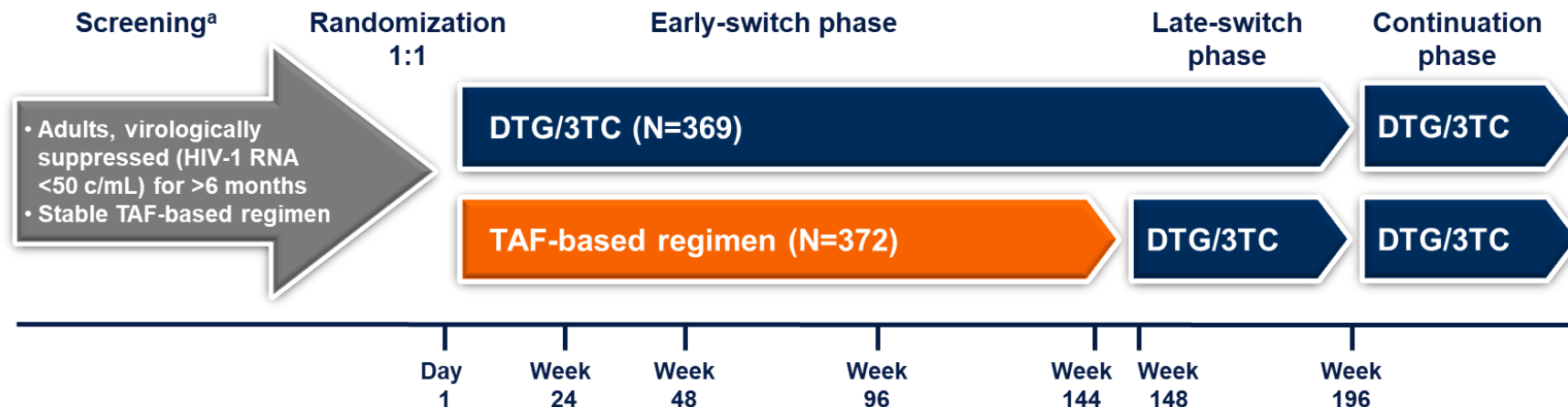
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Disclosure: Paul Benson participates in speakers bureaus for ViiV Healthcare.

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 regimen¹
- 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

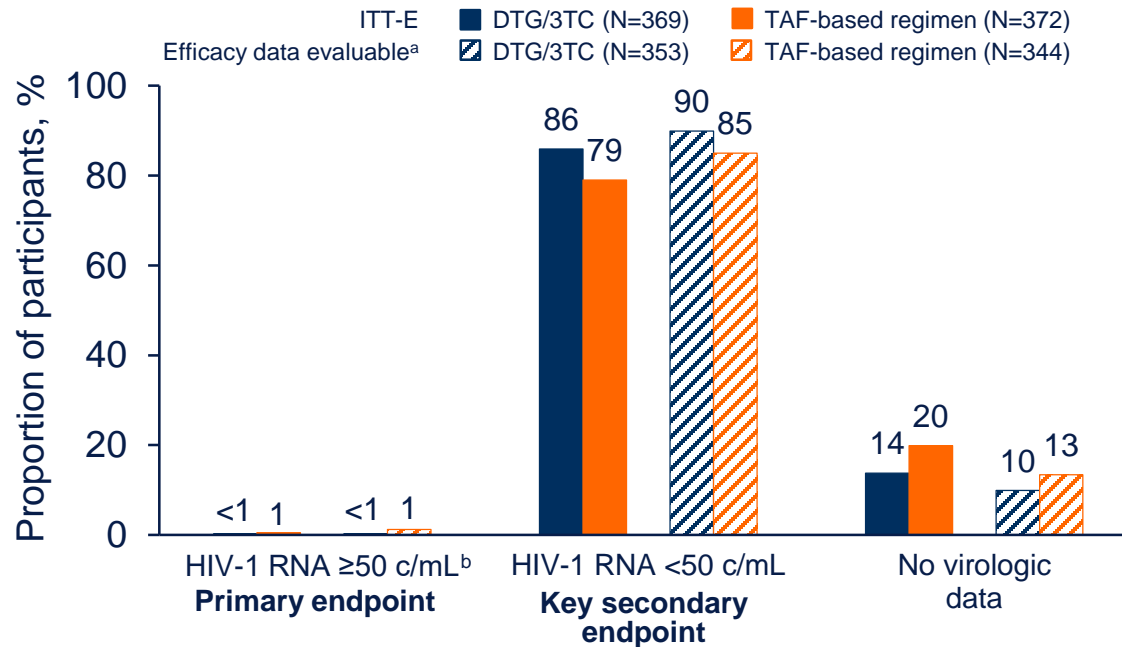


^aParticipants were eligible if they had ≥ 2 documented HIV-1 RNA measurements < 50 c/mL, no HBV infection or need for HCV therapy, no prior VF and no documented NRTI or INSTI resistance, and TAF/FTC + PI or INSTI or NNRTI as initial regimen.

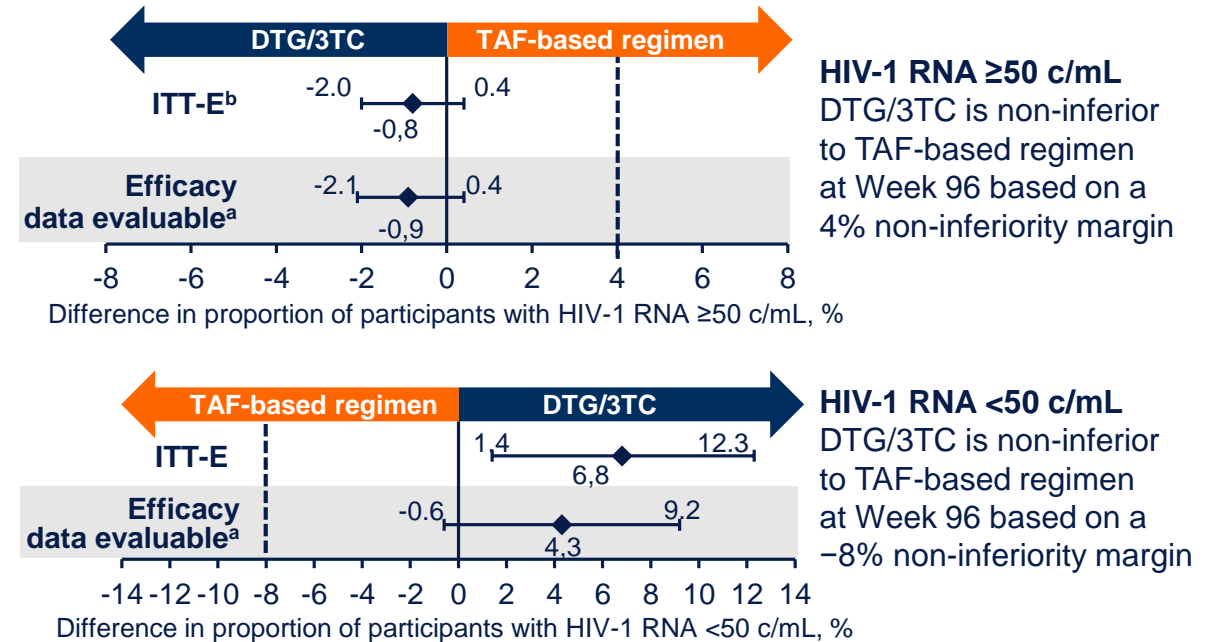
1. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT03446573>. Accessed January 26, 2021. 2. van Wyk et al. *Clin Infect Dis*. 2020;71:1920-1929. 3. van Wyk et al. HIV Glasgow 2020; Virtual. Slides O441.

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

Virologic outcomes (Snapshot analysis)



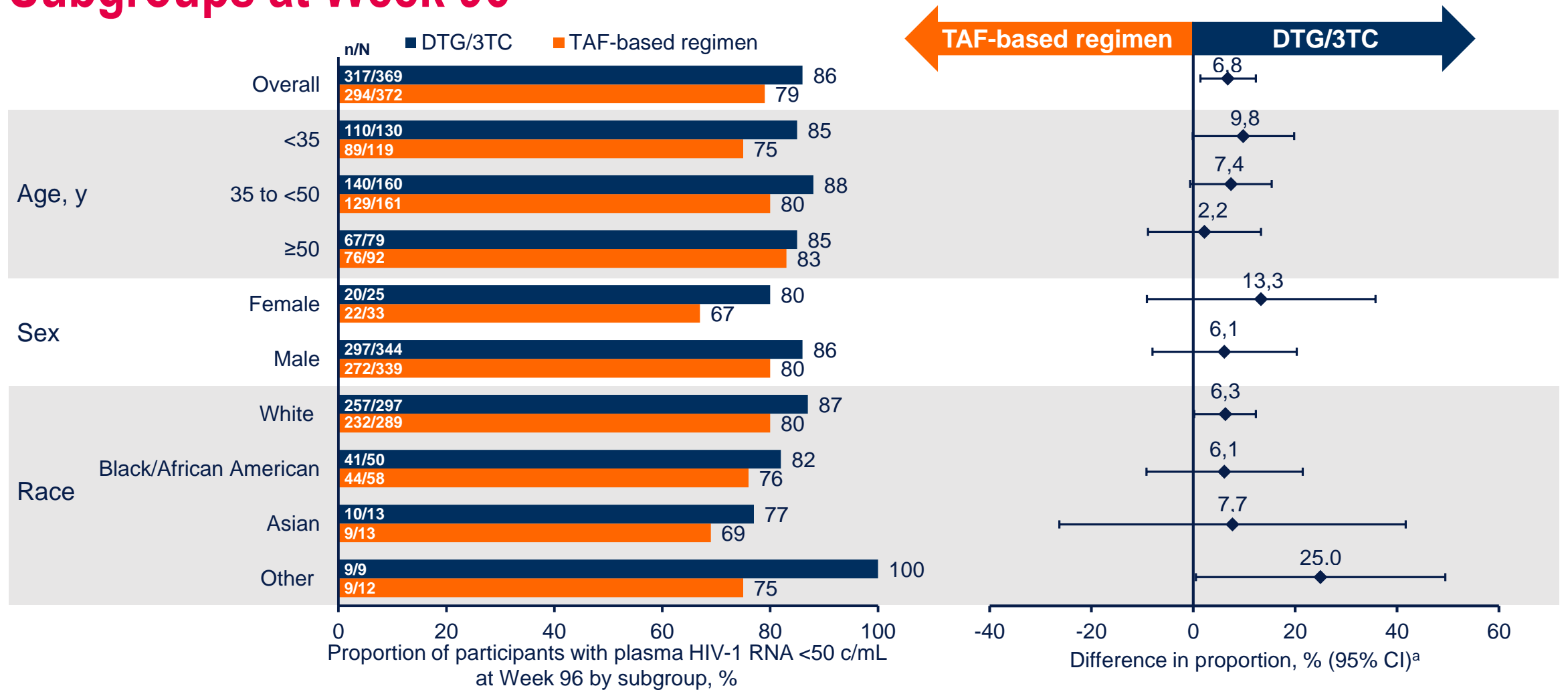
Adjusted treatment difference (95% CI)^c



- 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

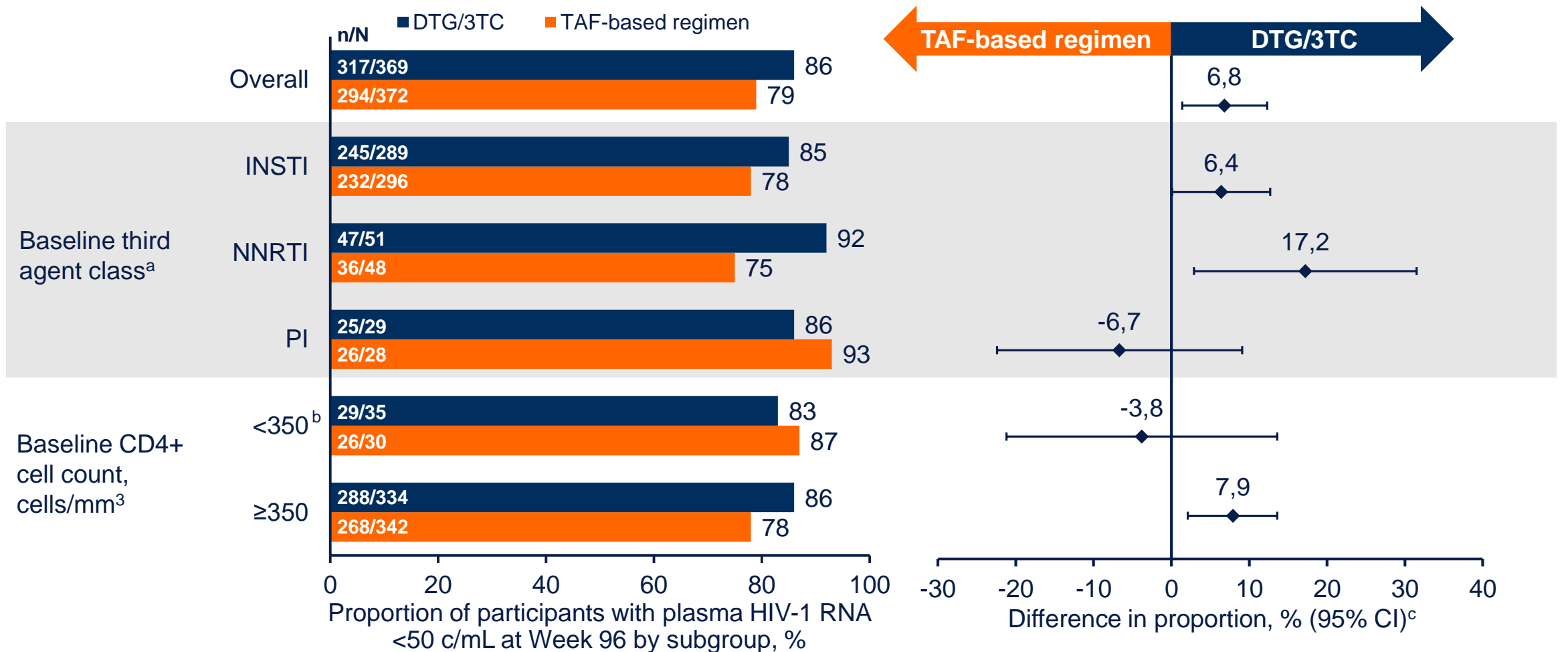
^aSensitivity analysis excluding 16 and 28 participants in the DTG/3TC and TAF-based regimen groups, respectively, because of no Week 96 HIV-1 RNA data due to effects of the COVID-19 pandemic. ^bPrimary endpoint (Snapshot virologic non-response, ITT-E). ^cBased on Cochran-Mantel-Haenszel stratified analysis (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



^aAdjusted 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



^aThe study population was stratified by baseline third agent class (PI, INSTI, or NNRTI). ^bIncludes 14 participants with baseline CD4+ cell count <200 cells/mm³: 71% (5/7) in the DTG/3TC group and 100% (7/7) in the TAF-based regimen group. ^cAdjusted 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		TAF-based regimen	
		n/N	%	n/N	%
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 groups¹

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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