

DURABLE EFFICACY OF DTG + 3TC IN GEMINI-1&-2: YEAR 3 SUBGROUP ANALYSES

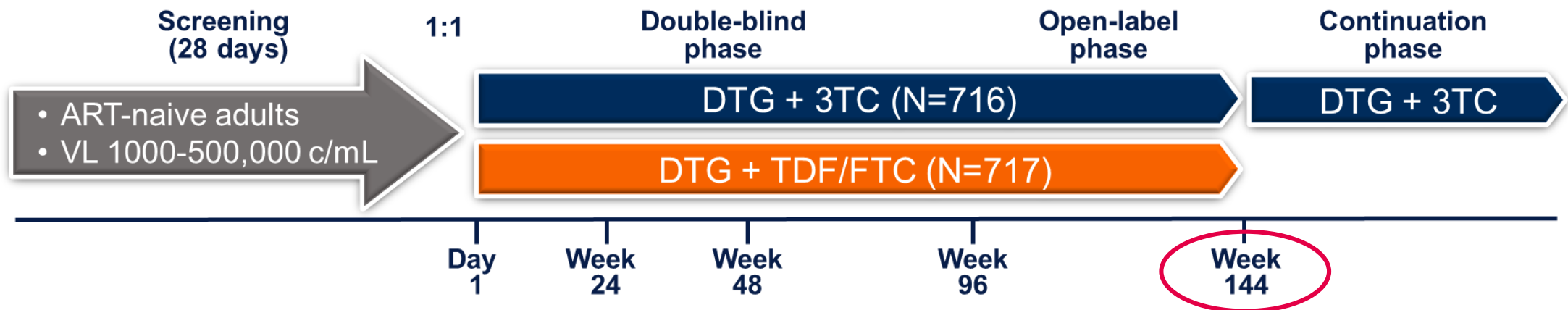
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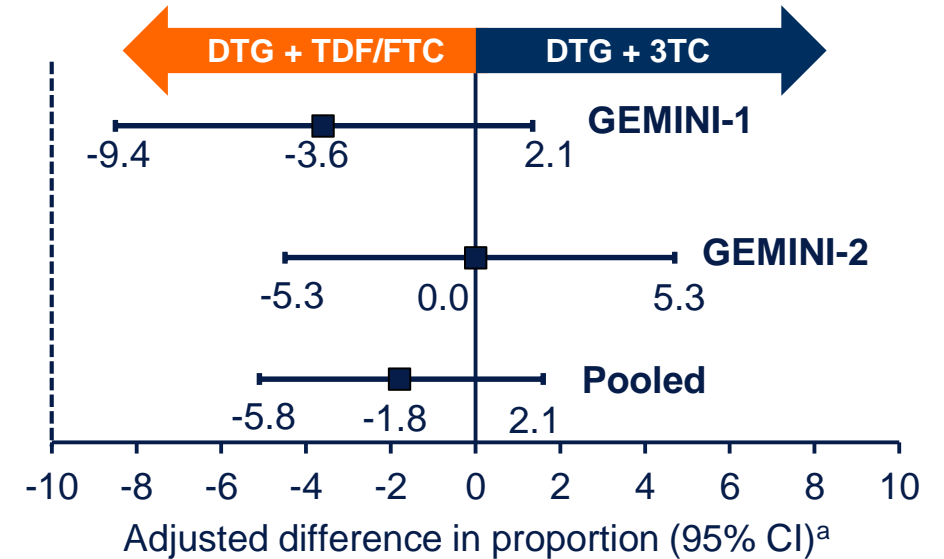
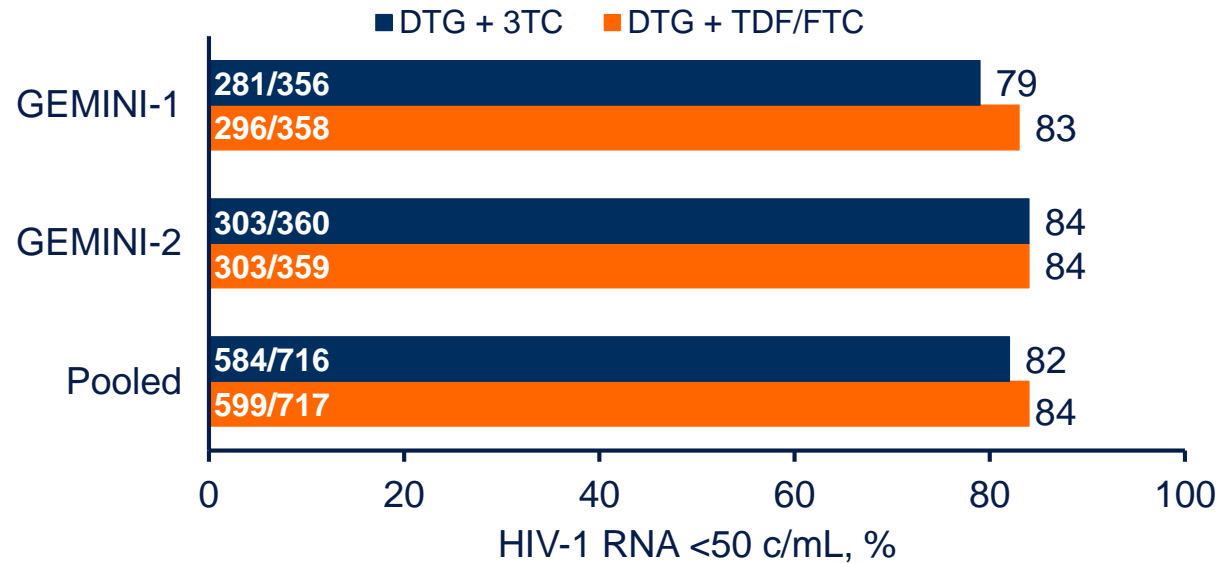
Background

- The GEMINI-1 and -2 studies (NCT02831673 and NCT02831764, respectively) are ongoing phase III, non-inferiority trials evaluating the efficacy and safety of initiating the 2-drug regimen DTG + 3TC in treatment-naive adults with HIV-1 infection compared with the 3-drug regimen DTG + TDF/FTC^{1,2}
- In the Weeks 48, 96, and 144 analyses of the GEMINI studies, DTG + 3TC demonstrated non-inferior efficacy vs DTG + TDF/FTC in ART-naive adults through 3 years of treatment³⁻⁵
- Here we present rates of virologic suppression (Snapshot) and safety results through Week 144 by demographic and baseline characteristics



1. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT02831673>. Accessed January 27, 2021. 2. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT02831764>. Accessed January 27, 2021. 3. Cahn et al. *Lancet*. 2019;393:143-155. 4. Cahn et al. *J Acquir Immune Defic Syndr*. 2020;83:310-318. 5. Cahn et al. HIV Glasgow 2020; Virtual. Poster P018.

DTG + 3TC Is Non-inferior to DTG + TDF/FTC at Week 144



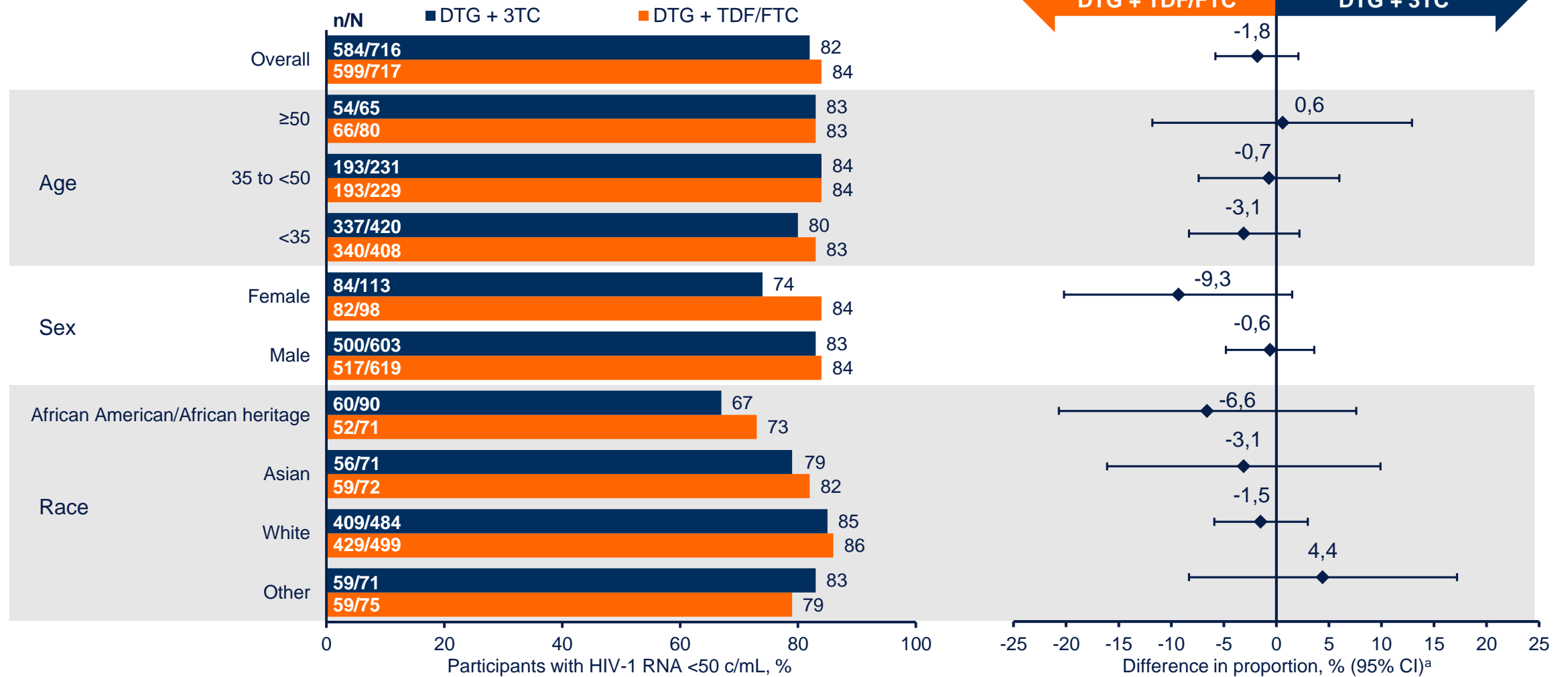
- Through Week 144, 12 participants in the DTG + 3TC group and 9 in the DTG + TDF/FTC group met protocol-defined CVW criteria; there were no treatment-emergent INSTI or NRTI resistance mutations
- 1 non-CVW participant with reported intermittent non-adherence in the DTG + 3TC group developed M184V at Week 132 (HIV-1 RNA 61,927 c/mL) and R263R/K at Week 144 (HIV-1 RNA 135 c/mL), conferring a 1.8-fold change in susceptibility to DTG

CVW, confirmed virologic withdrawal.

^aBased on Cochran-Mantel-Haenszel stratified analysis adjusting for baseline plasma HIV-1 RNA ($\leq 100,000$ vs $> 100,000$ c/mL) and baseline CD4+ cell count (≤ 200 vs > 200 cells/mm³). The pooled analysis was also adjusted for study (GEMINI-1 vs GEMINI-2).

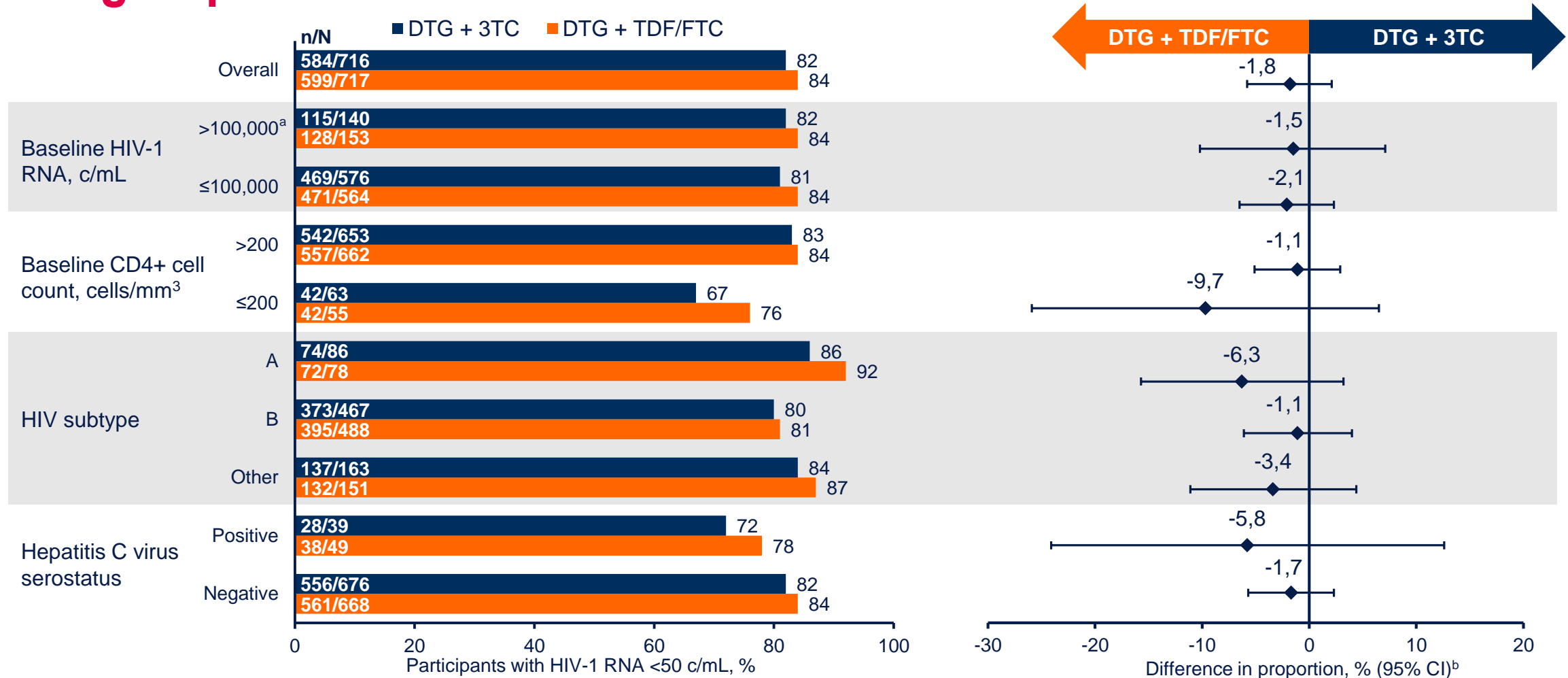
Cahn et al. HIV Glasgow 2020; Virtual. Poster P018.

HIV-1 RNA <50 c/mL Was Comparable Across Demographic Subgroups at Week 144



^aAdjusted difference (95% CI) for overall population (DTG + 3TC – DTG + TDF/FTC). Unadjusted difference for subgroups calculated by proportion on DTG + 3TC – proportion on DTG + TDF/FTC.

HIV-1 RNA <50 c/mL Was Comparable Across Baseline Disease Subgroups at Week 144



^aIncludes values for HIV-1 RNA >250,000 c/mL (DTG + 3TC, 41/51 [80%]; DTG + TDF/FTC, 37/46 [80%]), HIV-1 RNA >400,000 c/mL (DTG + 3TC, 15/18 [83%]; DTG + TDF/FTC, 19/24 [79%]), and HIV-1 RNA >500,000 c/mL (DTG + 3TC, 10/13 [77%]; DTG + TDF/FTC, 12/15 [80%]). ^bAdjusted difference for overall population (DTG + 3TC - DTG + TDF/FTC). Unadjusted difference for subgroups calculated by proportion on DTG + 3TC - proportion on DTG + TDF/FTC.

Frequency of All Adverse Events by Subgroup Through Week 144: Safety Population^a

Variable	Subgroup	DTG + 3TC		DTG + TDF/FTC	
		n/N	%	n/N	%
Overall	—	613/716	86	625/717	87
Age, y	<35	359/420	85	355/408	87
	35 to <50	203/231	88	197/229	86
	≥50	51/65	78	73/80	91
Sex	Female	90/113	80	76/98	78
	Male	523/603	87	549/619	89
Race	White	410/484	85	423/499	85
	African American/African heritage	76/90	84	66/71	93
	Asian	63/71	89	65/72	90
	Other	64/71	90	71/75	95
Baseline HIV-1 RNA, c/mL	≤100,000	495/576	86	490/564	87
	>100,000	118/140	84	135/153	88
Baseline CD4+ cell count, cells/mm ³	≤200	50/63	79	51/55	93
	>200	563/653	86	574/662	87

^aPost hoc analysis.

Weight Gain by Subgroup Through Week 144: Safety Population^a

Variable	Subgroup	DTG + 3TC		DTG + TDF/FTC	
		n	Mean (SD)	n	Mean (SD)
Change in weight from baseline, kg					
Overall	—	588	3.7 (6.8)	599	2.4 (7.6)
Sex	Female	86	2.7 (6.7)	79	1.8 (6.6)
	Male	502	3.8 (6.8)	520	2.5 (7.8)
Race	White	412	3.3 (6.8)	431	1.8 (7.4)
	African American/African heritage	62	3.9 (8.6)	51	4.2 (10.8)
	Asian	56	5.1 (5.9)	59	3.9 (6.3)
	Other	58	4.8 (5.4)	58	4.0 (6.4)
Change in BMI from baseline, kg/m ²					
Overall	—	587	1.2 (2.3)	599	0.8 (2.8)
Sex	Female	86	1.1 (2.6)	79	0.7 (2.4)
	Male	501	1.3 (2.2)	520	0.8 (2.8)
Race	White	411	1.1 (2.3)	431	0.6 (2.8)
	African American/African heritage	62	1.3 (2.8)	51	1.4 (3.5)
	Asian	56	1.7 (2.0)	59	1.4 (2.2)
	Other	58	1.6 (1.9)	58	1.4 (2.2)

^aPost hoc analysis.

Conclusions

- Treatment with DTG + 3TC was non-inferior to DTG + TDF/FTC in maintaining long-term virologic suppression in ART-naive adults with HIV-1 infection through Week 144
- Safety and weight gain by subgroups were consistent with overall Week 144 results
- Efficacy by subgroups was consistent with overall Week 144 study results, demonstrating that DTG + 3TC is effective at maintaining virologic suppression over the 3-year study period, regardless of baseline disease or demographic characteristics

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