

# PASO-DOBLE (GeSIDA 11720): Switch to DTG/3TC vs BIC/TAF/FTC in Virologically Suppressed Persons With HIV

## CCO Official Conference Coverage

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# PASO-DOBLE: Background

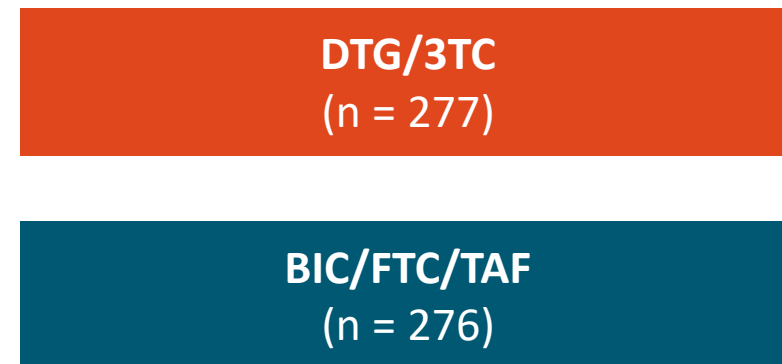
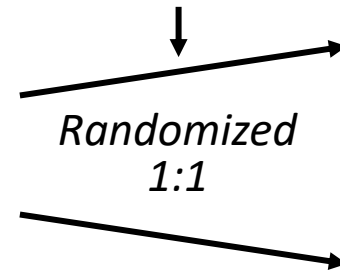
- In current treatment paradigm, ART is a lifelong requirement to control HIV
  - Efforts to optimize ART regimens for simplicity and tolerability both in first-line regimens and in later regimens are key for maintaining quality of life
- DTG/3TC and BIC/FTC/TAF are preferred first-line regimens and are also recommended by guidelines as switch regimens in persons with virologic suppression in certain cases<sup>1-3</sup>
  - Role of DTG, BIC, TAF in potential weight gain unclear
- Current study compares the safety and tolerability (including weight gain) of DTG/3TC and BIC/FTC/TAF as switch regimens for persons with virologic suppression<sup>4</sup>

# PASO-DOBLE: Study Design

- Multicenter, randomized, open-label phase IV trial in Spain

Adults with HIV-1 RNA <50 c/mL for ≥24 wk; current ART with ≥1 pill/day including either COBI booster, EFV, or TDF; no earlier VF or ART resistance; no previous use of DTG or BIC; no chronic HBV  
(N = 553)

*Stratified by TAF  
use at baseline,  
sex at birth*



- Primary endpoint: plasma HIV-1 RNA ≥50 c/mL at Wk 48 by FDA Snapshot with noninferiority margin of 4%
- Key secondary endpoints: efficacy, safety, tolerability, weight change

# PASO-DOBLE: Baseline Characteristics

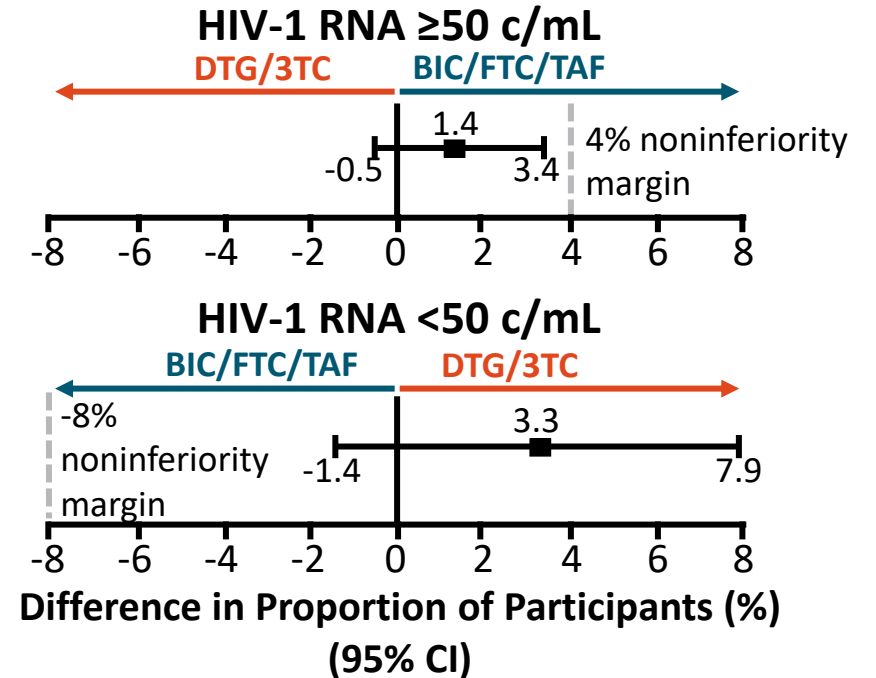
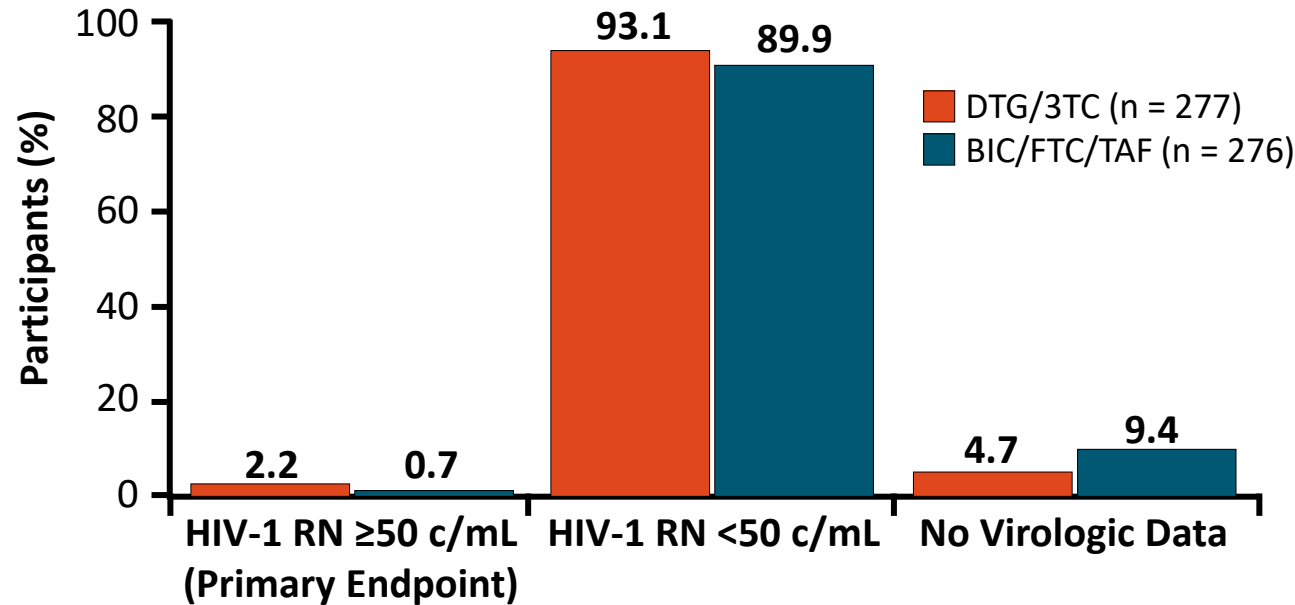
Parameter	DTG/3TC (n = 277)	BIC/FTC/TAF (n = 276)
Mean age, yr (range)	50 (41-57)	51 (39-58)
Female sex at birth, n (%)	74 (26.7)	73 (26.4)
Race/ethnicity, n (%)		
▪ White	201 (72.6)	201 (72.8)
▪ Latino/a	66 (23.8)	67 (24.3)
▪ Black	4 (1.4)	5 (1.8)
▪ Other/unknown	6 (2.2)	2 (1.1)
Mean total time on ART, yr (range)	11.7 (7.2-19.3)	11.1 (7.0-19.2)
▪ Mean time with HIV <50 c/ml, mo (range)	103.4 (43.0-170.2)	97.7 (41.5-163.3)
▪ Mean time on prior ART, mo (range)	66.2 (43.5-97.0)	62.8 (41.1-88.7)
Mean CD4+ cell count, cells/mm <sup>3</sup> (range)	712 (516-918)	684 (473-859)
▪ CD4+ count <350 cells/mm <sup>3</sup> , n (%)	26 (9.4)	24 (8.7)
▪ Mean CD4+ nadir, cells/mm <sup>3</sup> (range)	293 (144-472)	302 (159-476)
Mean BMI, kg/m <sup>2</sup> (range)	25.1 (22.3-28.49)	24.8 (22.2-28.2)
▪ BMI >25 kg//m <sup>2</sup> , n (%)	143 (51.8)	134 (48.8)

# PASO-DOBLE: Baseline ART Regimens

Agent/Class, n (%)	DTG/3TC (n = 277)	BIC/FTC/TAF (n = 276)
<b>NRTI 1</b>		
▪ TAF	77 (27.8)	78 (28.3)
▪ ABC	59 (21.3)	52 (18.8)
▪ TDF	92 (33.2)	103 (37.3)
▪ No NRTI 1	49 (17.7)	43 (15.6)
<b>NRTI 2</b>		
▪ 3TC	70 (25.3)	64 (23.2%)
▪ FTC	182 (65.7)	190 (68.8%)
▪ None	25 (9.0)	22 (8.0%)
<b>Core drug</b>		
▪ NNRTI only	138 (49.8)	141 (51.1)
▪ INSTI only	44 (15.9)	49 (17.8)
▪ PI only	93 (33.6)	82 (29.7)
▪ >1 core drugs	2 (0.7)	4 (1.4)

# PASO-DOBLE: Virologic Efficacy

Snapshot Outcomes at Wk 48 (ITT-E Population)



- By Wk 48,  $\geq 1$  virologic blip in 5.8% (16/277) receiving DTG/3TC and in 9.4% (26/276) receiving BIC/FTC/TAF;  $P = .106$ 
  - Through Wk 48, 98 vs 152 total blips in those receiving DTG/3TC and BIC/FTC/TAF, respectively
- Confirmed virologic failure through Wk 48 in 1 participant receiving BIC/FTC/TAF vs 0 in those receiving DTG/3TC; no cases of emergent resistance in either arm

# PASO-DOBLE: Adverse Events

Event, n (%)	DTG/3TC (n = 277)	BIC/FTC/TAF (n = 276)	P Value
Any AE	207 (74.7)	216 (78.3)	.327
Grade 3/4 AEs	3 (1.1)	10 (3.6)	.049
Serious AEs	12 (4.3)	13 (4.7)	.831
Drug-related AEs	19 (6.9)	27 (9.8)	.213
AEs leading to withdrawal*	1 (0.4)	2 (0.7)	.561

\*DTG/3TC: general discomfort and arthromyalgia, n = 1; BIC/TAF/FTC: insomnia, n = 1; sleep disturbance, n = 1.

Organ System Event in ≥10% of Either Arm, n (%)	DTG/3TC (n = 277)	BIC/FTC/TAF (n = 276)
Infections	36.8	45.3
Musculoskeletal	19.5	18.5
Gastrointestinal	17.3	10.5
Metabolic	13.7	9.4
Psychiatric	9.7	13.4

- No study drug-related AEs or AEs leading to death in either arm

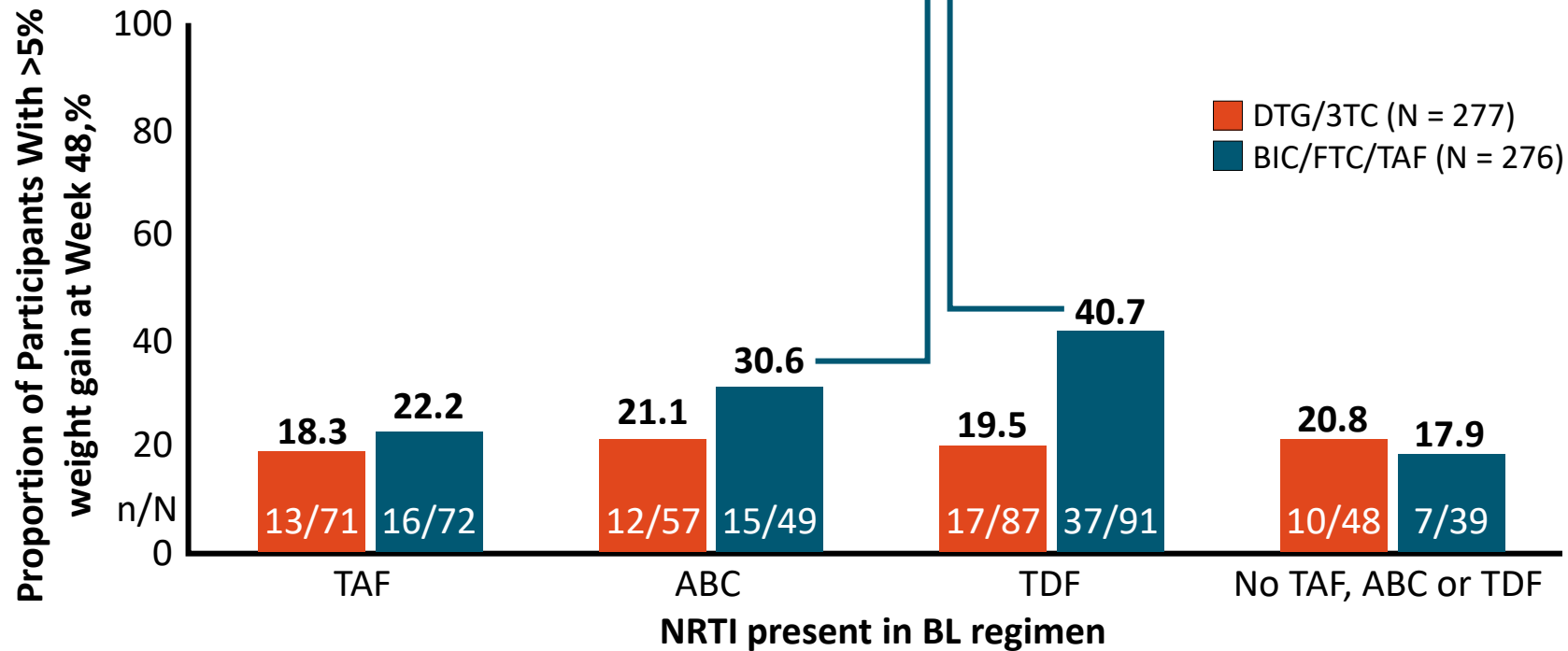
# PASO-DOBLE: Body Weight Outcomes

Outcome at Wk 48	DTG/3TC (n = 265)	BIC/FTC/TAF (n = 254)	Mean Adjusted Diff or OR (95% CI)
Weight change from BL, kg	+0.89	+1.81	+0.92 (0.17-1.66)
BMI change from BL, kg/m <sup>2</sup>	+0.32	+0.64	+0.32 (0.06-0.58)
Percent of participants with weight gain >5%	20.0	29.9	1.81* (1.19-2.76) <i>P</i> = .006

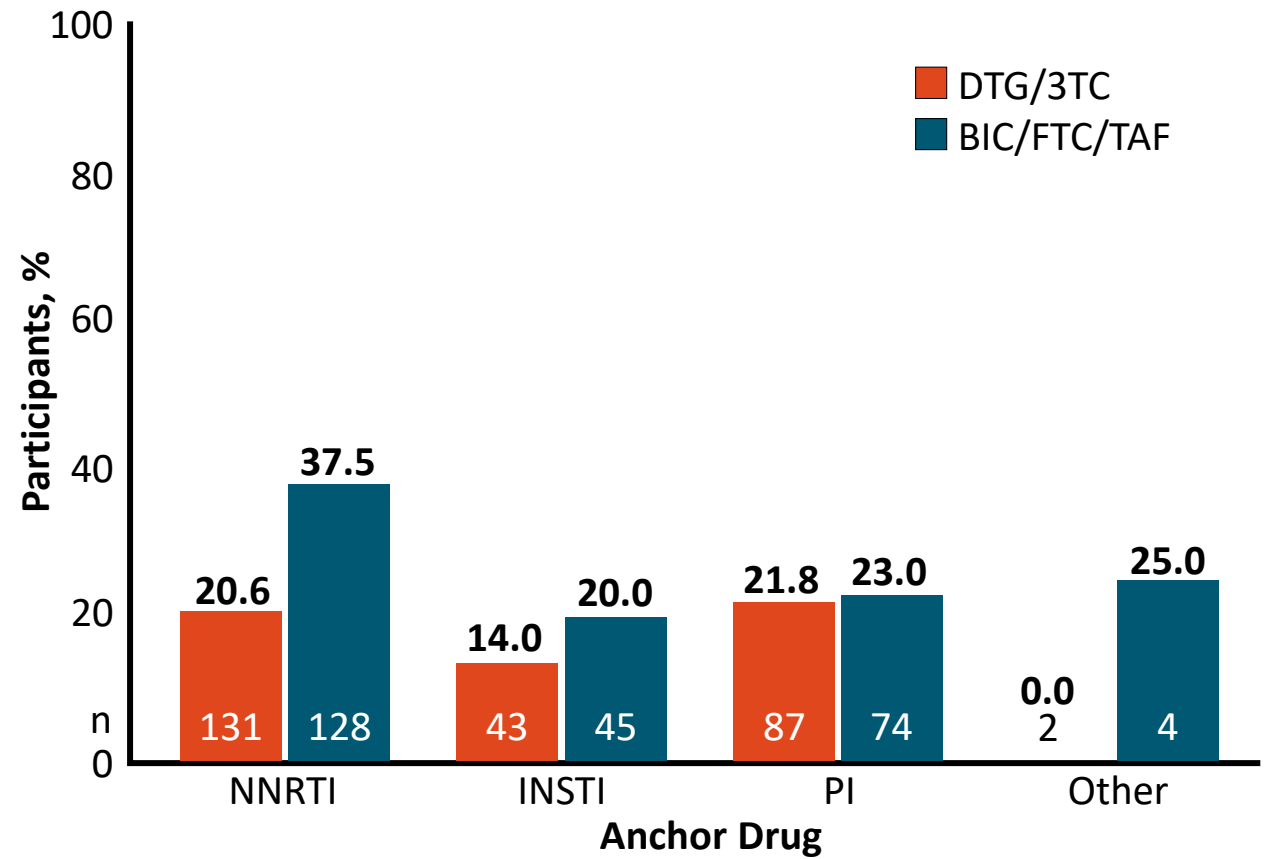
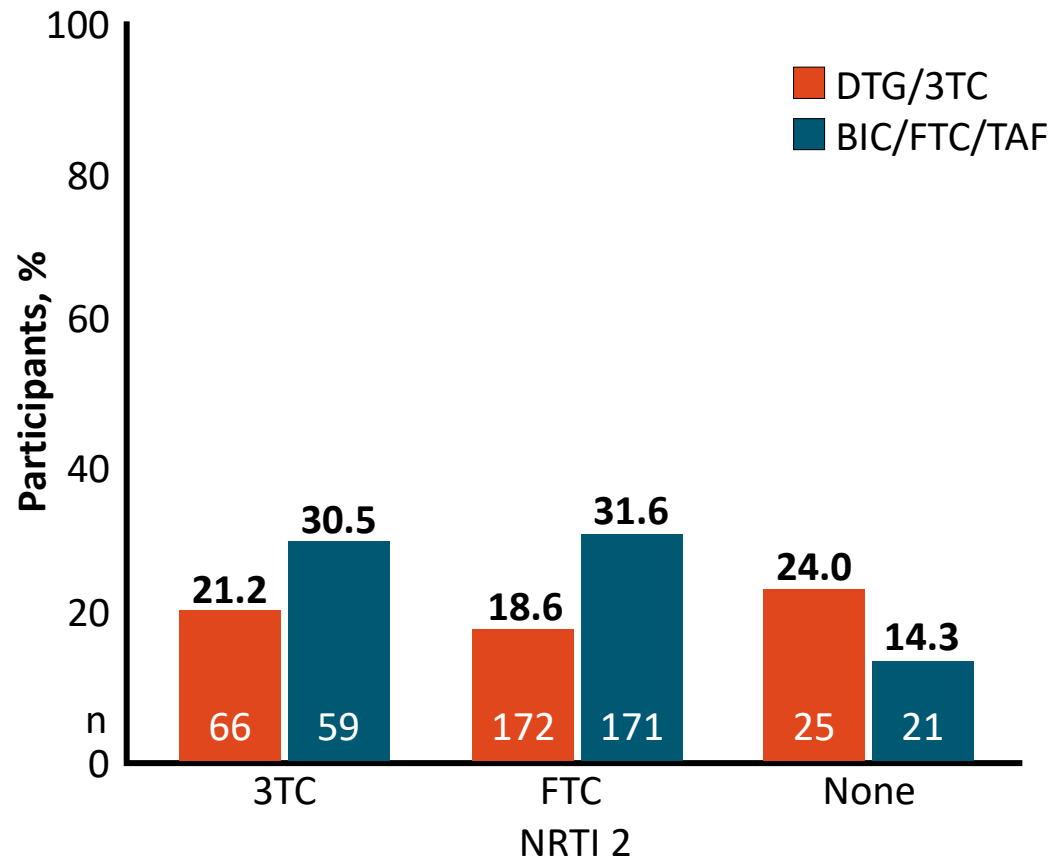
\*Adjusted OR.

# PASO-DOBLE: Body Weight Outcomes by Baseline NRTI

- Change in weight with BIC/TAF/FTC may depend on NRTI of previous regimen
  - In **DTG/3TC** arm, proportion with >5% weight gain was similar regardless of BL NRTI
  - In **BIC/FTC/TAF** arm, proportion with >5% weight gain was highest after switch from TDF or ABC



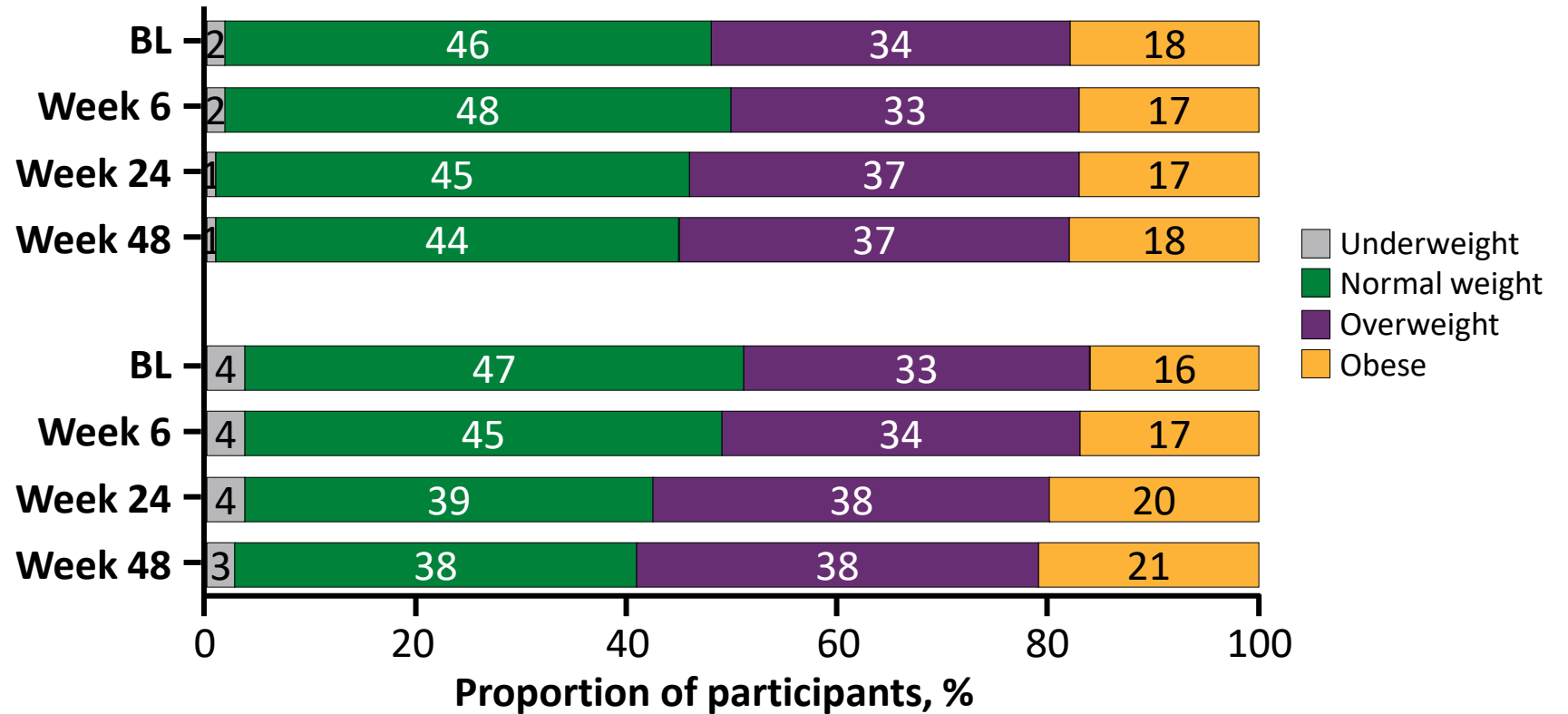
# PASO-DOUBLE: Body Weight Outcomes by Baseline NRTI and Core Drug



# PASO-DOBLE: BMI Distribution by Visit

**DTG/3TC**  
(n = 277)

**BIC/FTC/TAF**  
(n = 276)



# PASO-DOBLE (GeSIDA 11720): Investigators' Conclusions

- In persons with HIV who are virologically suppressed on ART, switch ART to DTG/3TC was noninferior to switch to BIC/FTC TAF in terms of virologic efficacy
  - DTG/3TC and BIC/FTC/TAF had similar high barriers to resistance
  - Both regimens were well tolerated, with few discontinuations due to adverse effects
- Switch to BIC/FTC/TAF led to significantly more weight gain than switch to DTG/3TC
  - Extent of weight gain may depend on prior ART regimen and core drug

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