

DTG + 3TC versus DTG + TDF-FTC as Initial ART  
**GEMINI 1 and GEMINI 2: Week 48 Data**

# DTG + 3TC versus DTG + TDF-FTC as Initial ART

## GEMINI 1 and 2: Background

### Study Design: GEMINI 1 and 2

- **Background:**

- Two identical, double-blind, multinational, noninferiority, randomized controlled trials that compared initial antiretroviral therapy (ART) of dolutegravir plus lamivudine (DTG + 3TC) versus dolutegravir plus tenofovir-DF-emtricitabine (DTG + TDF-FTC)

- **Enrollment Criteria:**

- Treatment-naïve adults
- HIV RNA 1,000-500,000 copies/mL
- No NRTI, INSTI, or major PI mutations
- No chronic HBV
- No need for HCV therapy
- Not pregnant or breastfeeding

**DTG + 3TC  
(Dual ART)  
n = 716**

**DTG + TDF-FTC  
(Triple ART)  
n = 717**

Primary endpoint: % with HIV RNA <50 copies/mL at 48 weeks by ITT

# DTG + 3TC versus DTG + TDF-FTC as Initial ART

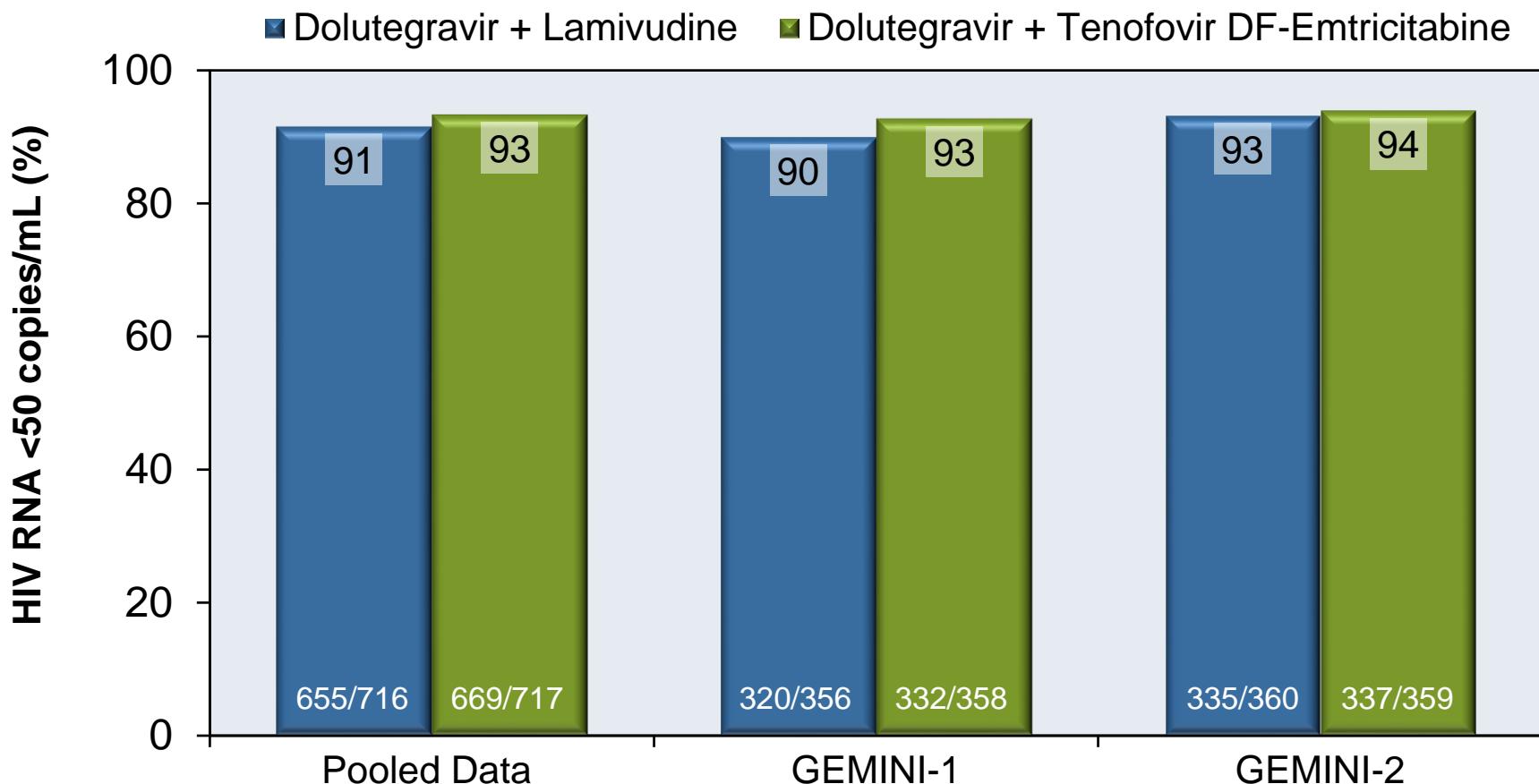
## GEMINI 1 and 2: Baseline Characteristics

GEMINI 1 and 2 Baseline Characteristics		
Characteristic	DTG + 3TC (n = 716)	DTG + TDF-FTC (n = 717)
Age, years, median (IQR)	32 (26-40)	33 (26-42)
Female, n (%)	113 (16)	98 (14)
White, n (%)	480 (67)	497 (69)
Black or African American, n (%)	99 (14)	76 (11)
CD4 cell count, mean (SD)	462 (219.2)	461.3 (213.1)
CD4 count $\leq$ 200 cells/mm <sup>3</sup> , n (%)	63 (9)	55 (8)
HIV RNA ( $\log_{10}$ copies/mL)	4.42 (0.66)	4.45 (0.65)
$\leq$ 100,000 copies/mL, n (%)	576 (80)	564(79)
>100,000 copies/mL, n (%)	140 (20)	153 (21)

Source: Cahn P, et al. Lancet. 2019;393:143-55.

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results

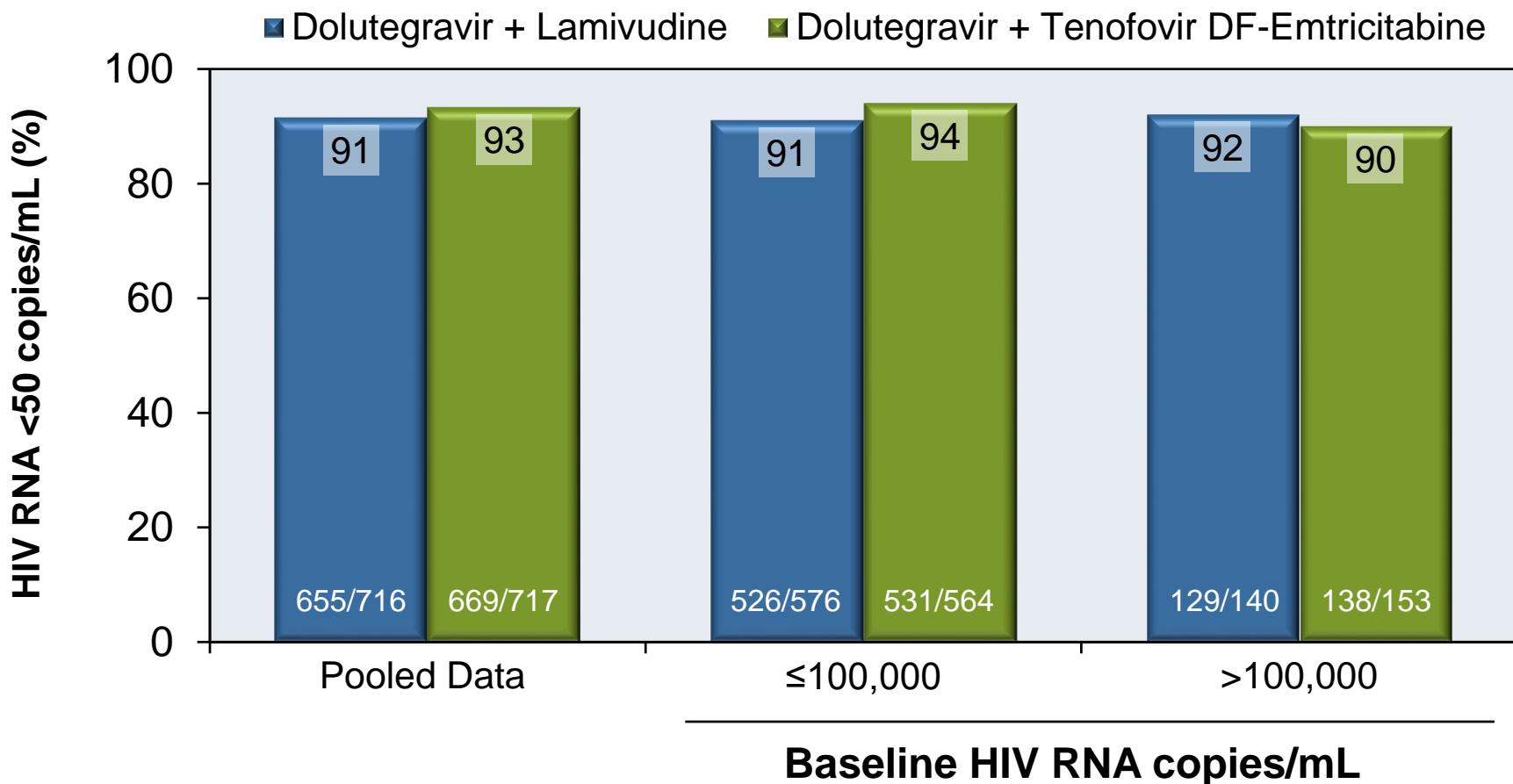
## Week 48 Virologic Response (Intention-to-Treat Analysis)



Source: Cahn P, et al. Lancet. 2019;393:143-55

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results by Baseline HIV RNA Level

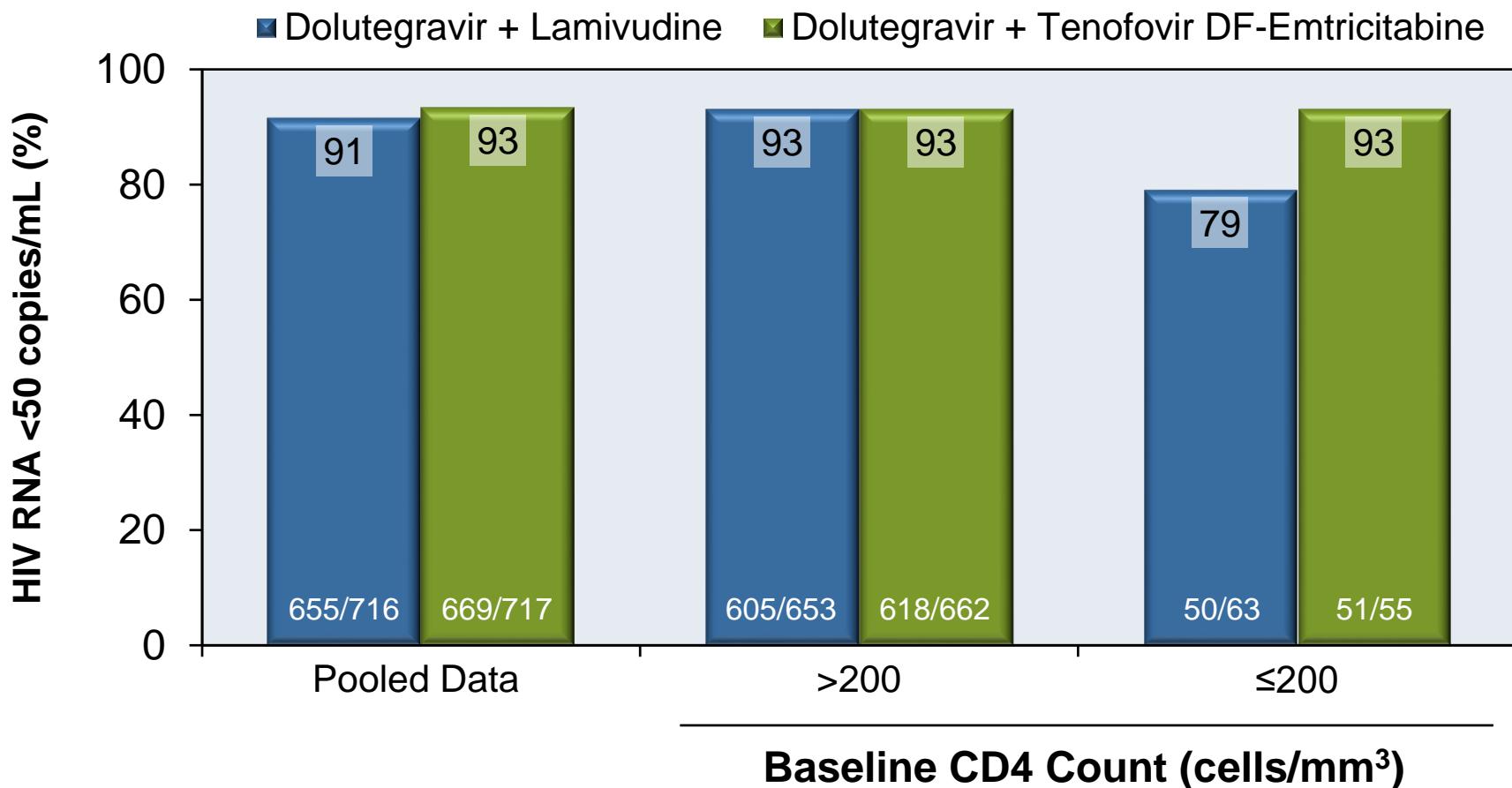
Week 48 Virologic Response (Intention-to-Treat Analysis)



Source: Cahn P, et al. Lancet. 2019;393:143-55.

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results by Baseline CD4 Cell Count

Week 48 Virologic Response (Intention-to-Treat Analysis)

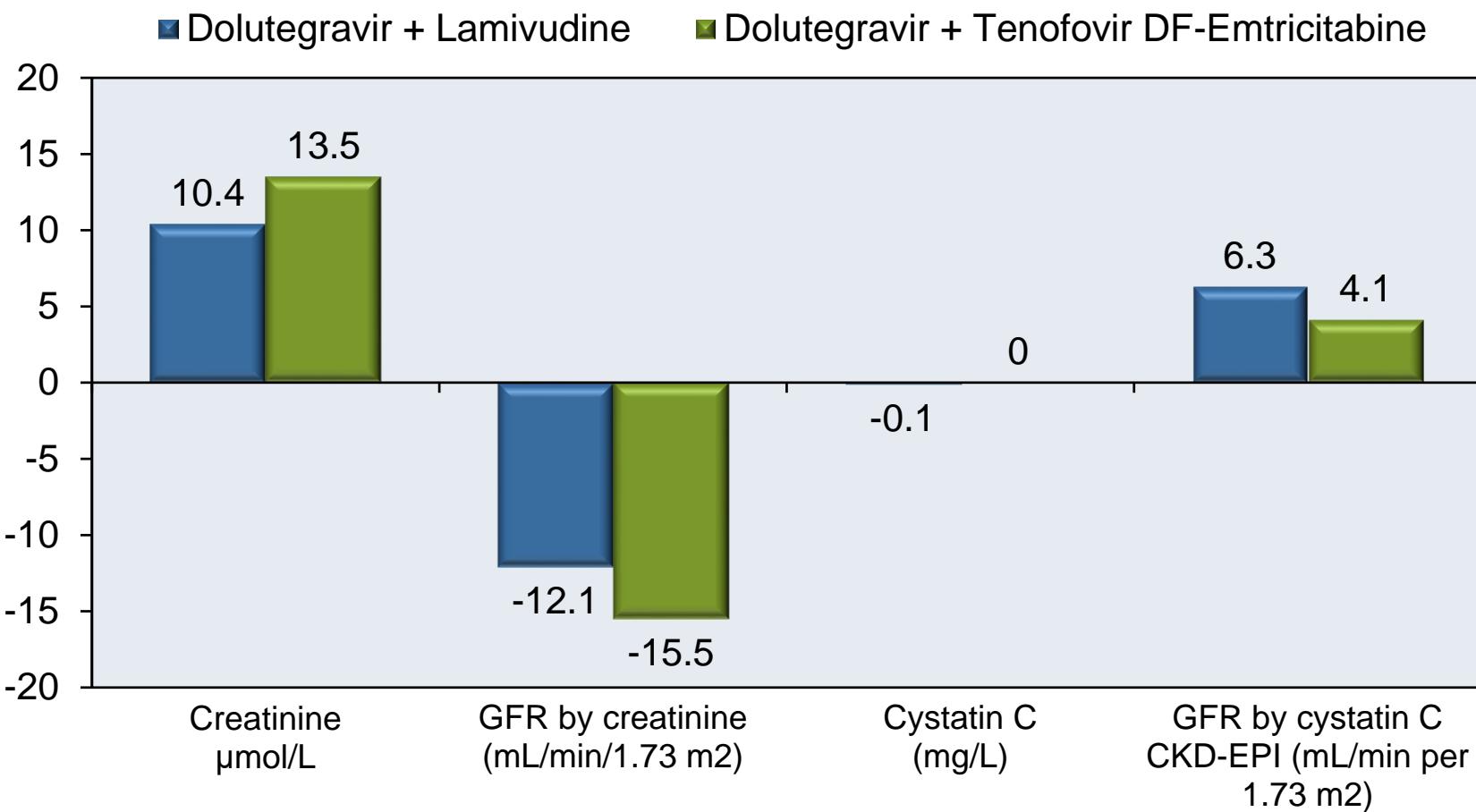


Source: Cahn P, et al. Lancet. 2019;393:143-55.

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results

## Week 48 Changes in Renal Function

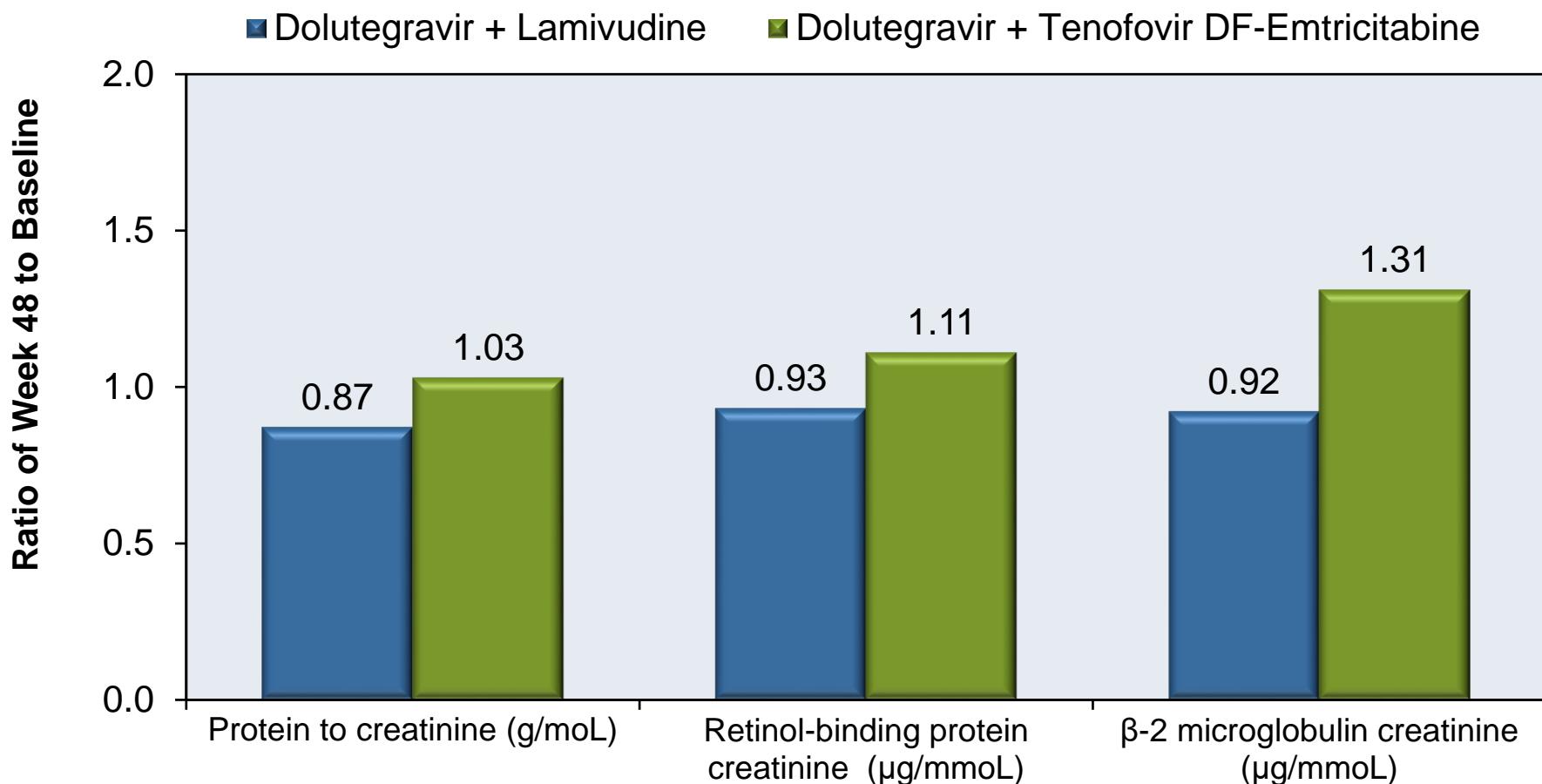
Adjusted Median Change from Baseline



Source: Cahn P, et al. Lancet. 2019;393:143-55.

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results

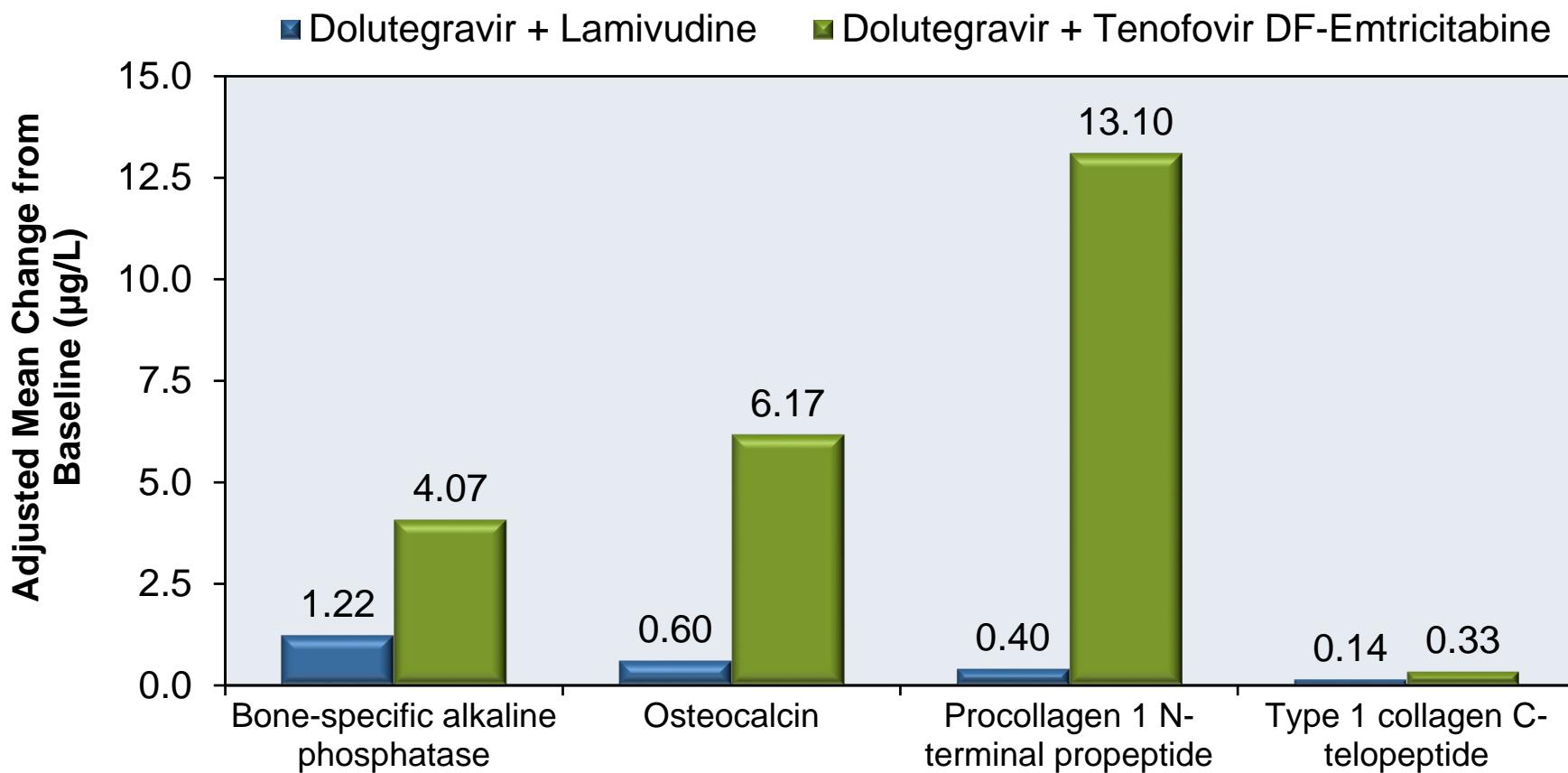
## Week 48 Changes in Markers of Renal Proximal Tubulopathy



Source: Cahn P, et al. Lancet. 2019;393:143-55.

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results

## Week 48 Changes in Serum Bone Biomarkers



Source: Cahn P, et al. Lancet. 2019;393:143-55.

# DTG + 3TC versus DTG + TDF-FTC as Initial ART

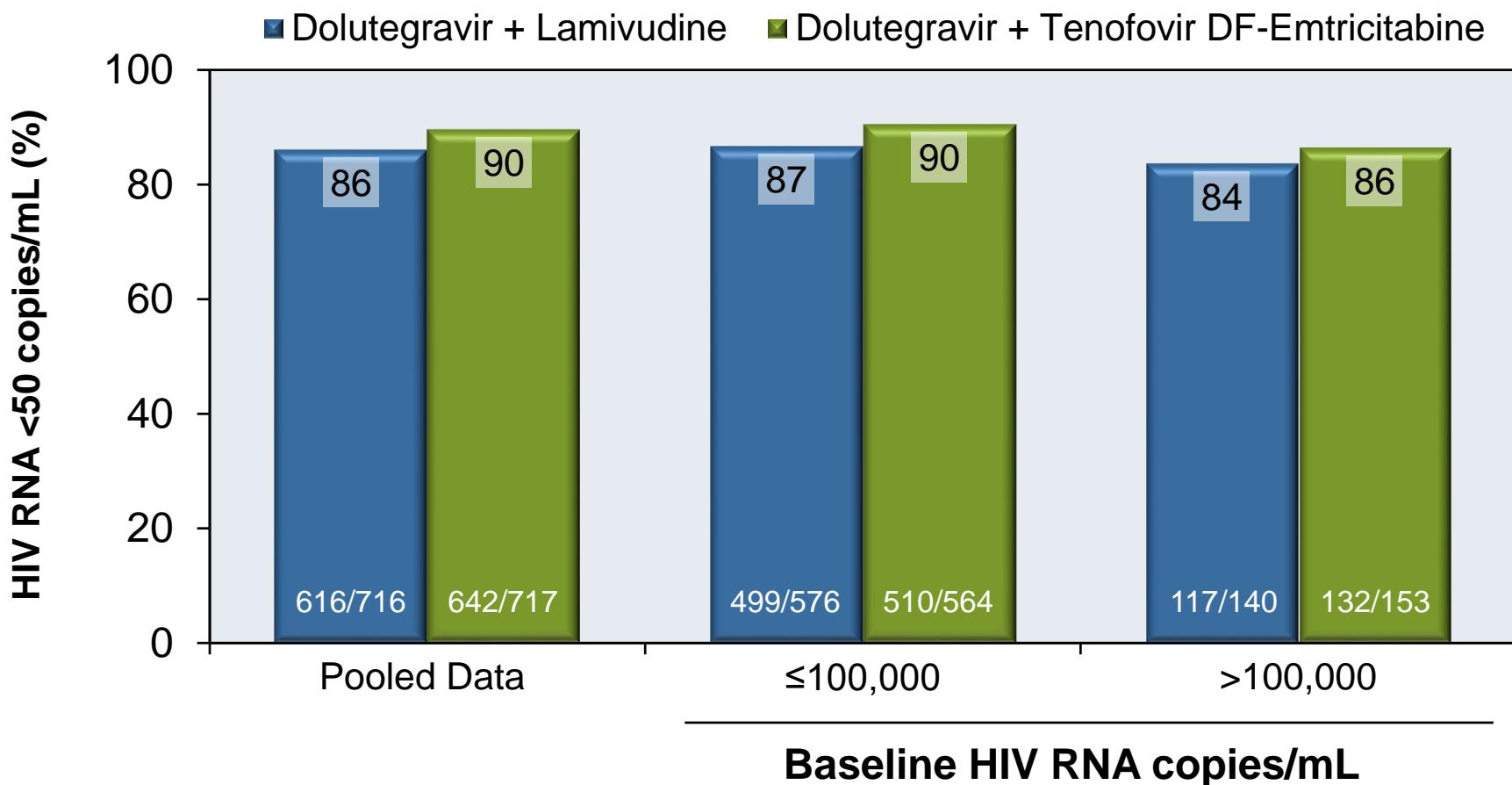
## GEMINI 1 & 2: Conclusion

**Interpretation:** “The non-inferior efficacy and similar tolerability profile of dolutegravir plus lamivudine to a guideline-recommended three-drug regimen at 48 weeks in ART-naive adults supports its use as initial therapy for patients with HIV-1 infection.”

DTG + 3TC versus DTG + TDF-FTC as Initial ART  
**GEMINI 1 and GEMINI 2: Week 96 Data**

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results by Baseline HIV RNA Level

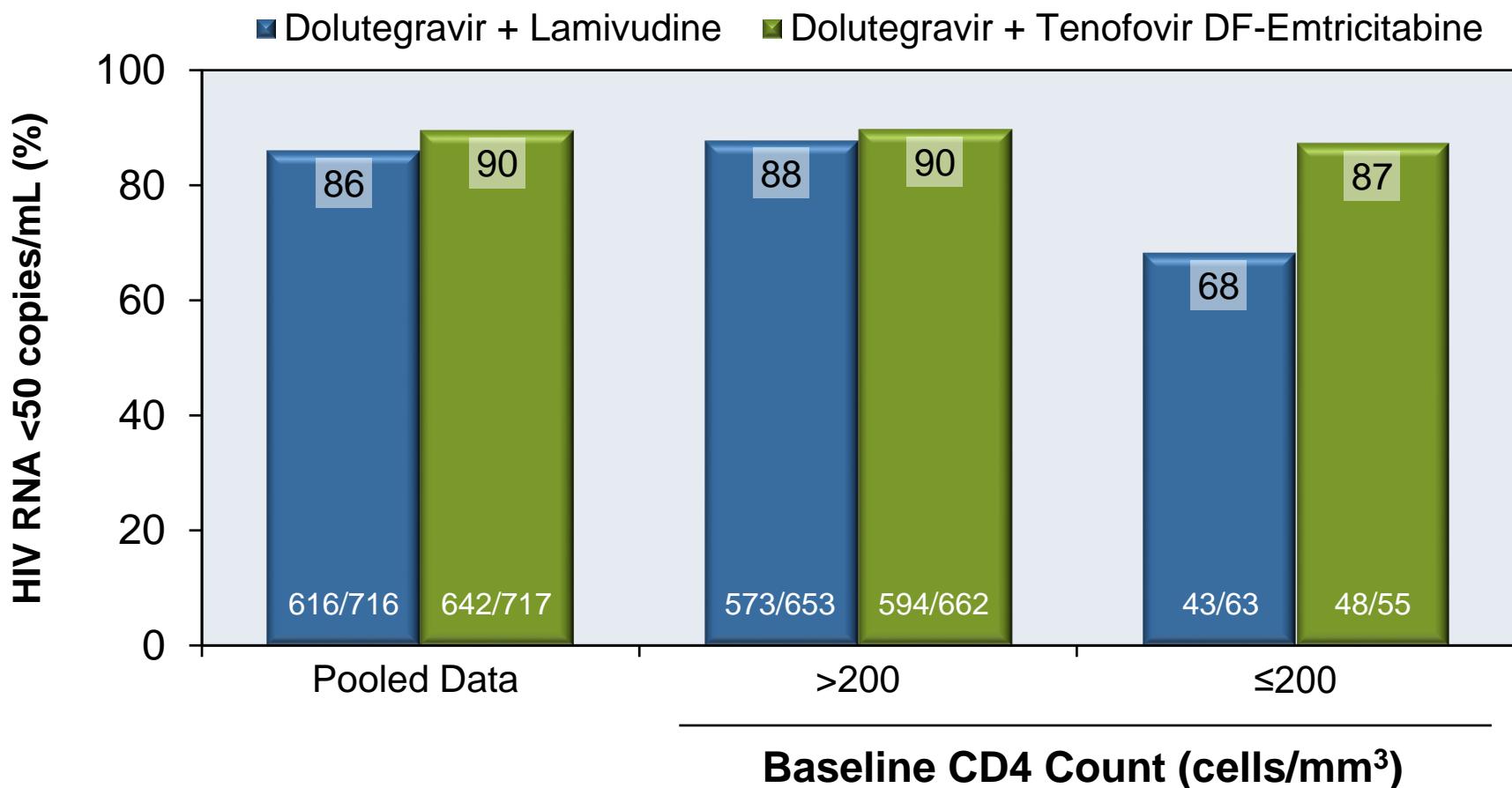
## Week 96 Virologic Response (Intention-to-Treat Analysis)



Source: Cahn P, et al. J Acquir Immune Defic Syndrome. 2019 Dec 10. Epub ahead of print

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results by Baseline CD4 Cell Count

## Week 96 Virologic Response (Intention-to-Treat Analysis)

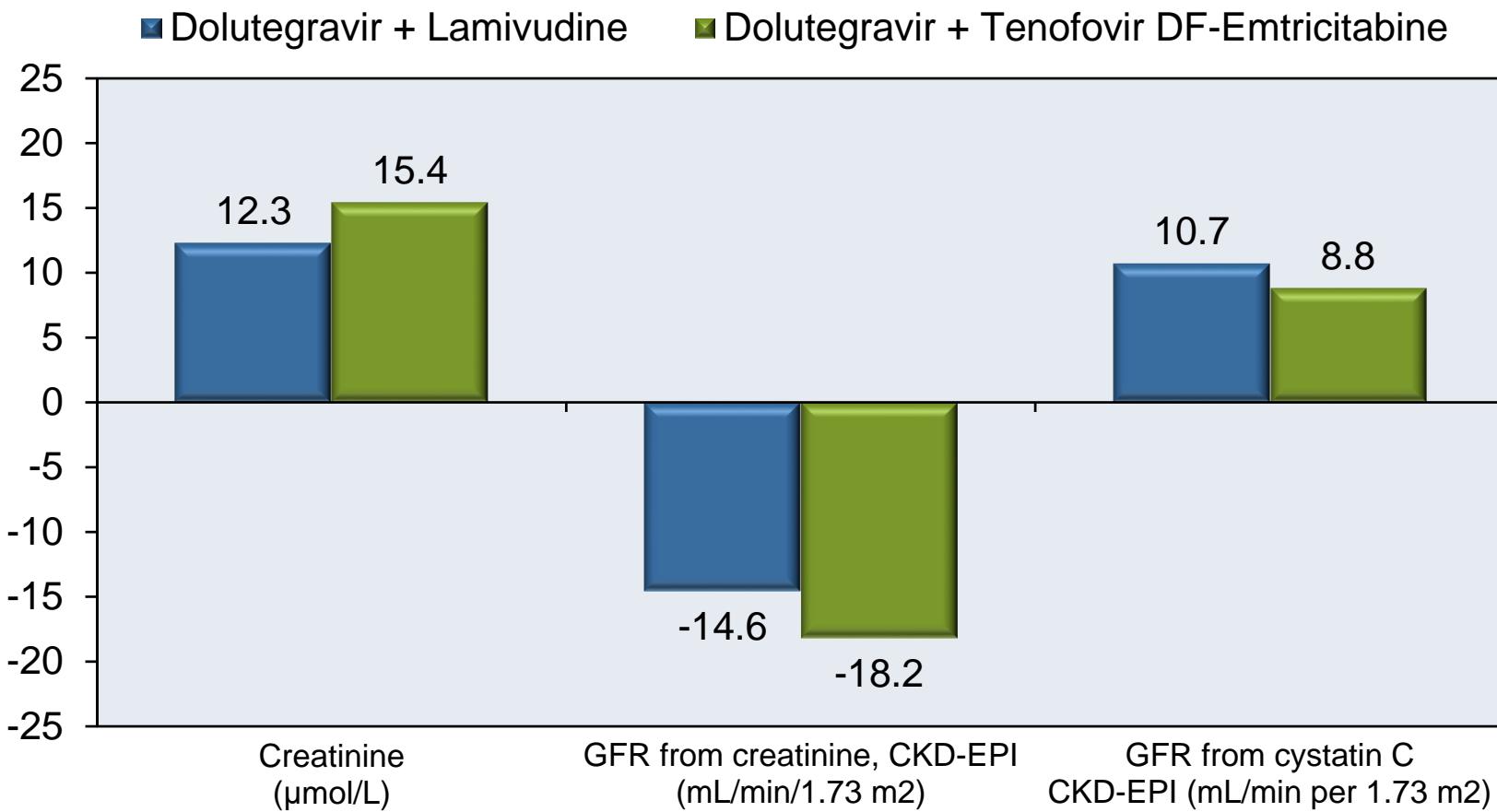


Source: Cahn P, et al. J Acquir Immune Defic Syndrome. 2019 Dec 10. Epub ahead of print

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results

## Week 96 Changes in Renal Function

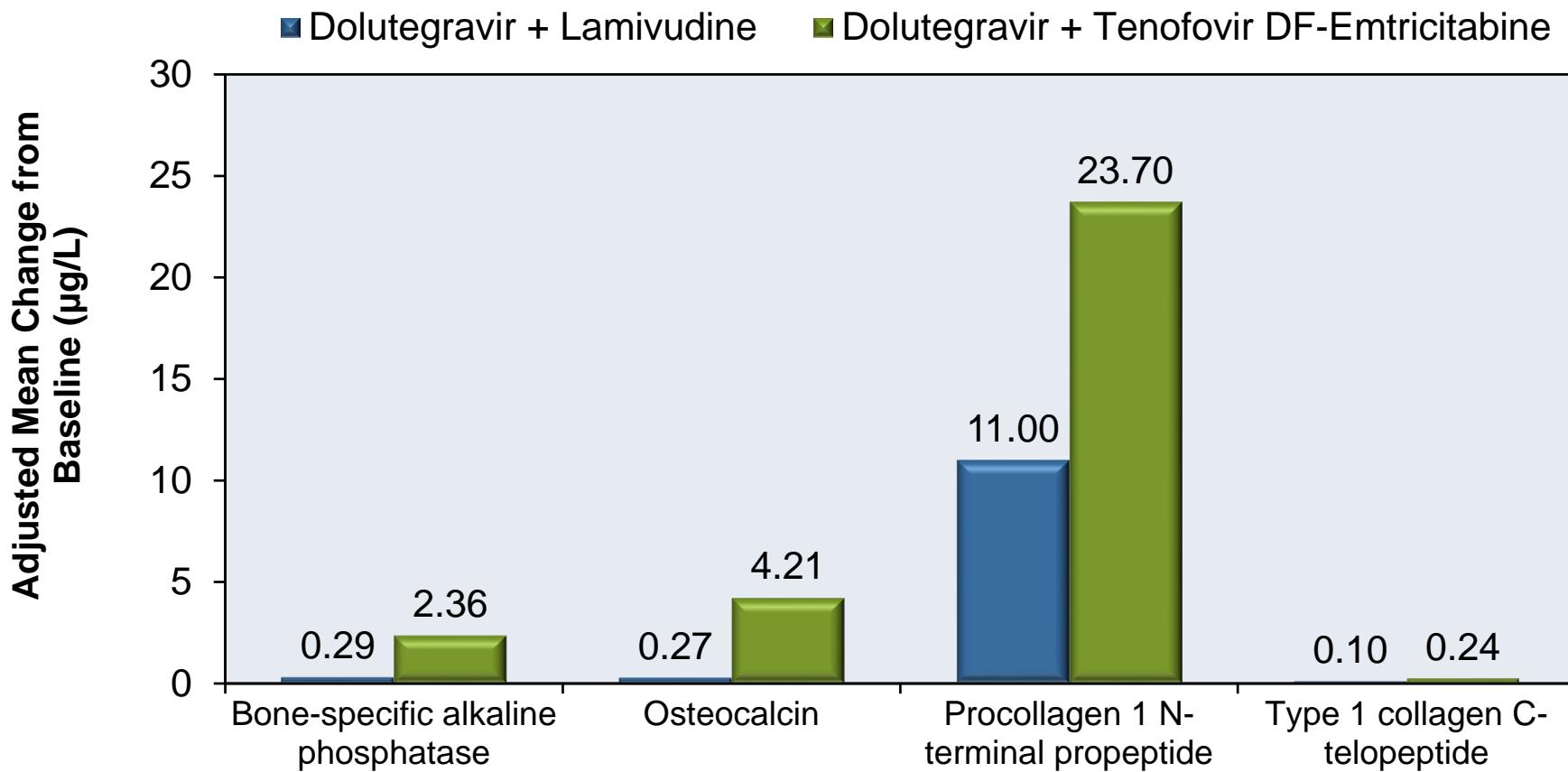
Adjusted Median Change from Baseline



Source: Cahn P, et al. J Acquir Immune Defic Syndrome. 2019 Dec 10. Epub ahead of print

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Results

## Week 96 Changes in Serum Bone Biomarkers



Source: Cahn P, et al. J Acquir Immune Defic Syndrom. 2019 Dec 10. Epub ahead of print

# DTG + 3TC versus DTG + TDF-FTC as Initial ART GEMINI 1 and 2: Week 96 Conclusion

**Conclusion:** “Consistent with 48-week data, dolutegravir + lamivudine demonstrated long-term, non-inferior efficacy vs dolutegravir + tenofovir disoproxil fumarate/emtricitabine without increased risk of treatment emergent resistance, supporting its use in treatment-naive HIV-1–infected individuals.”

# Acknowledgment

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