

Dolutegravir + Boosted-Darunavir as Maintenance Therapy  
**DUALIS**

# Switch to Boosted DRV + DTG vs Continue Boosted DRV + 2 NRTI's DUALIS: Background

## Study Design: DUALIS

- **Background:**

- Randomized, open label, multicenter phase 3 non-inferiority trial comparing a switch to boosted darunavir + dolutegravir to continued boosted darunavir + 2 NRTIs

- **Enrollment Criteria:**

- Age  $\geq 18$  years
- HIV RNA  $< 50$  copies/mL for  $> 6$  months
- Taking boosted darunavir + 2 NRTI's
- One HIV RNA level  $> 200$  copies/mL within past 6 months allowed, as long as subsequently returned to  $< 50$  copies/mL
- Estimated GFR  $> 50$  mL/min
- No active hepatitis B, AIDS-defining condition, or severe hepatitis impairment

*Switch Regimen*

**Boosted darunavir +  
dolutegravir**

(n = 131)

*Maintain Regimen*

**Boosted darunavir +  
2 NRTIs**

(n = 132)

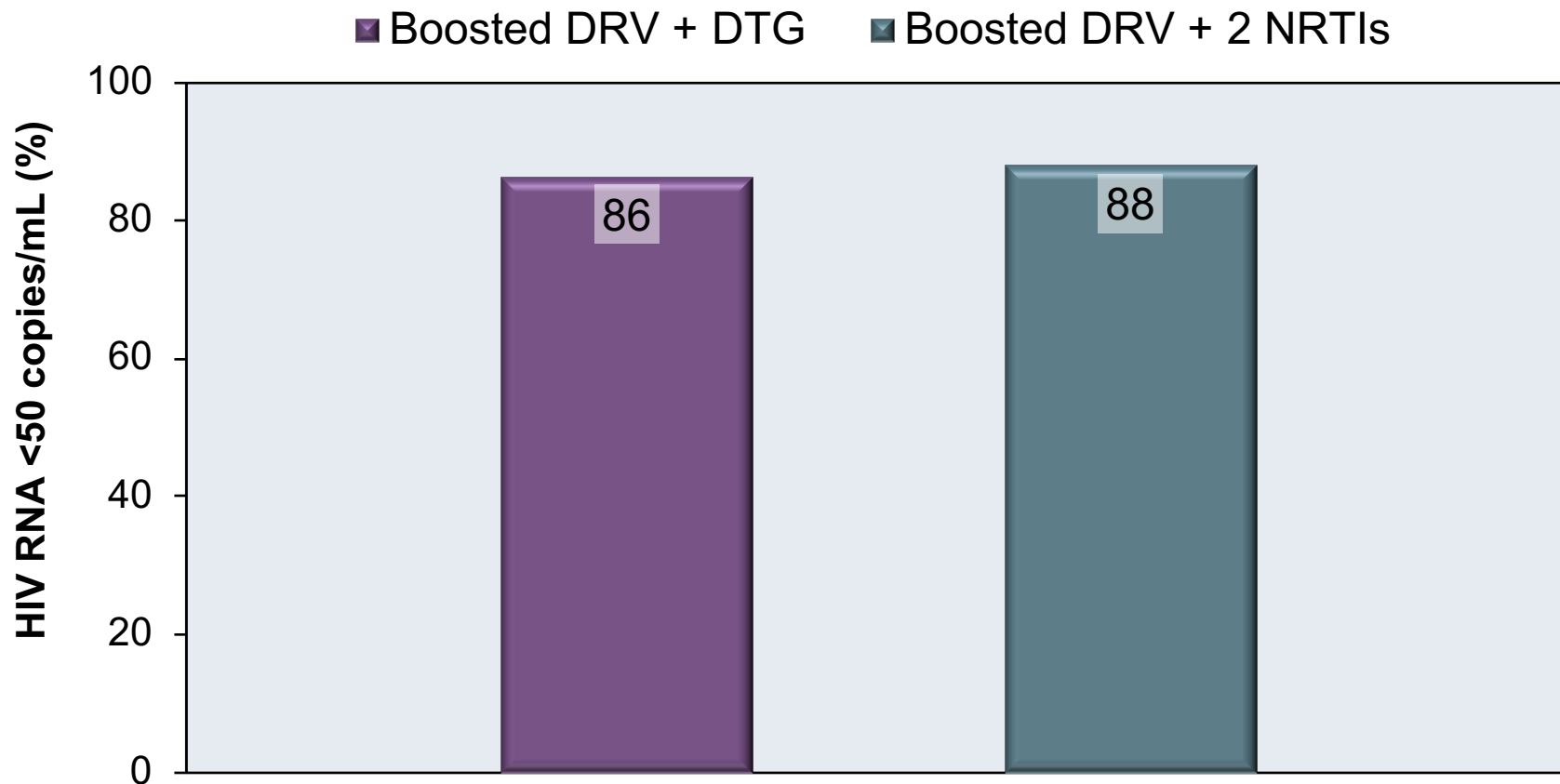
Primary endpoint: virologic response at 48 weeks by FDA snapshot

# Switch to Boosted DRV + DTG vs Continue Boosted DRV + 2 NRTI's DUALIS: Baseline Characteristics

Characteristic	Boosted DRV + DTG (n = 131)	Boosted DRV + 2 NRTIs (n = 132)
Age, years, median (IQR)	47 (39-55)	48 (40-53)
Male sex, n (%)	115 (88)	122 (92)
White, n (%)	118 (90)	118 (89)
MSM, n (%)	90 (69)	92 (70)
eGFR, median (IQR), mL/min	92 (70-104)	92 (81-106)
Baseline CD4, median (IQR)	609 (401-818)	585 (453-823)
NRTIs at baseline, n (%)		
Tenofovir-DF-emtricitabine	110 (84)	94 (71)
Tenofovir-alafenamide-emtricitabine	11 (8)	13 (10)
Abacavir-lamivudine	9 (7)	23 (17)

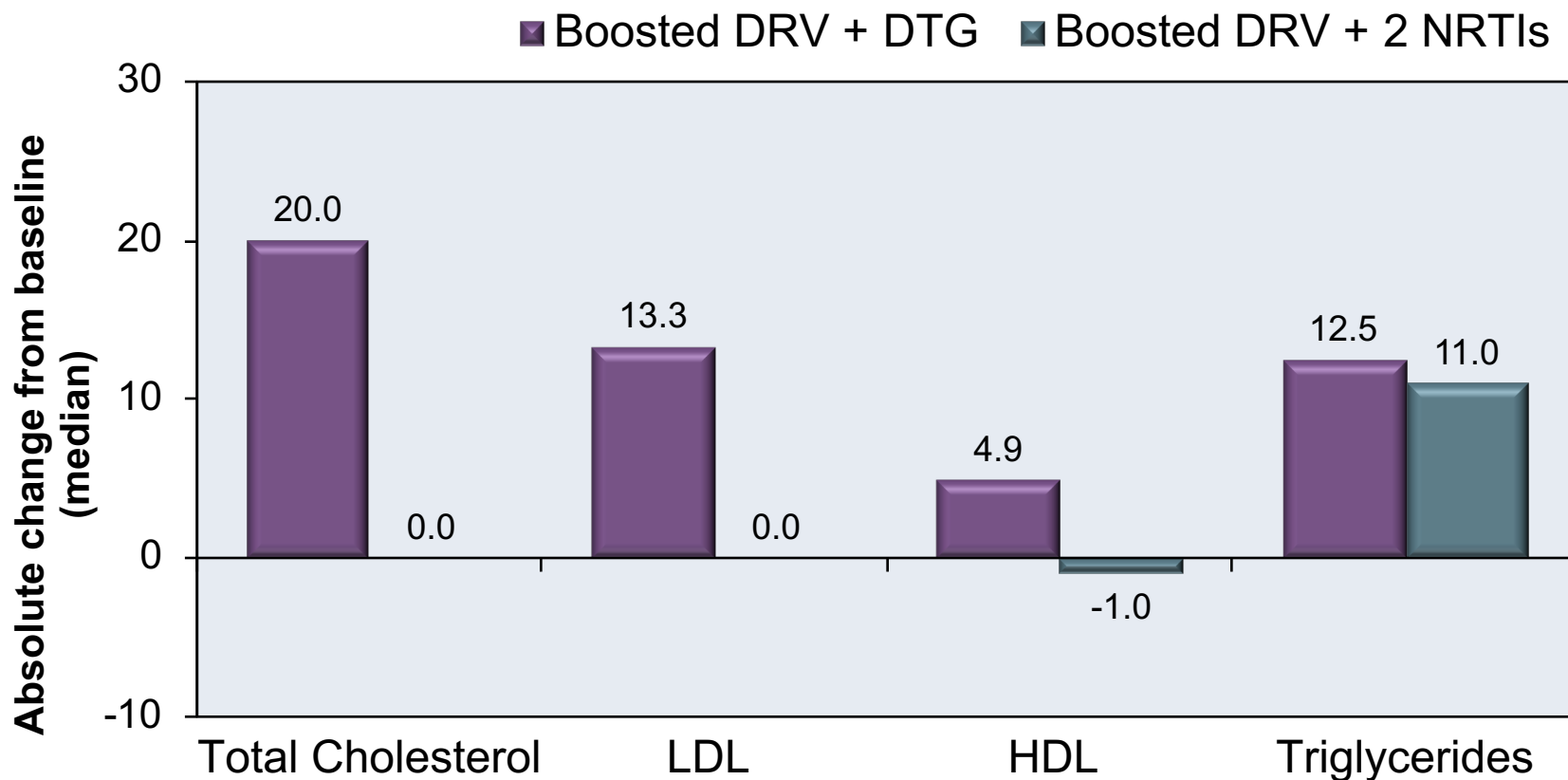
# Switch to Boosted DRV + DTG vs Continue Boosted DRV + 2 NRTI's DUALIS: Results

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



# Switch to Boosted DRV + DTG vs Continue Boosted DRV + 2 NRTI's DUALIS: Results

## Week 48 Changes in Serum Lipid Parameters



# Switch to Boosted DRV + DTG vs Continue Boosted DRV + 2 NRTI's DUALIS: Conclusions

**Conclusions:** “Switching to dolutegravir plus boosted darunavir was noninferior to continuing 2 nucleoside reverse transcriptase inhibitors plus boosted darunavir in subjects already treated with 2 nucleoside reverse transcriptase inhibitors plus boosted darunavir.”

# Acknowledgment

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