

Dual Maintenance ART with RTV-Boosted Darunavir + Lamivudine  
**DUAL-GESIDA**

# Dual Maintenance ART with RTV-Boosted Darunavir + Lamivudine

## DUAL GESIDA: Study Design

### Study Design: DUAL GESIDA

- **Background:** Phase IV, randomized, parallel group, open-label, non-inferiority trial conducted at multiple sites in Spain to compare the efficacy of simplification to dual maintenance therapy with ritonavir-boosted darunavir + lamivudine versus continuation of darunavir-anchored triple ART
- **Inclusion Criteria (n = 249 analyzed)**
  - Age over 18
  - On once-daily darunavir + ritonavir + TDF-FTC or ABC-3TC for  $\geq 4$  weeks
  - HIV RNA <50 copies/mL for  $\geq 6$  months
  - Negative hepatitis B surface Ag
  - No resistance to darunavir or lamivudine
- **Treatment Arms (once daily)**
  - Darunavir + ritonavir + lamivudine
  - Continue current regimen

**DRV + RTV + 3TC  
(DUAL ART)**  
(n = 126)

**DRV + RTV + 2 NRTI's  
(CONTINUE TRIPLE ART)**  
(n = 123)

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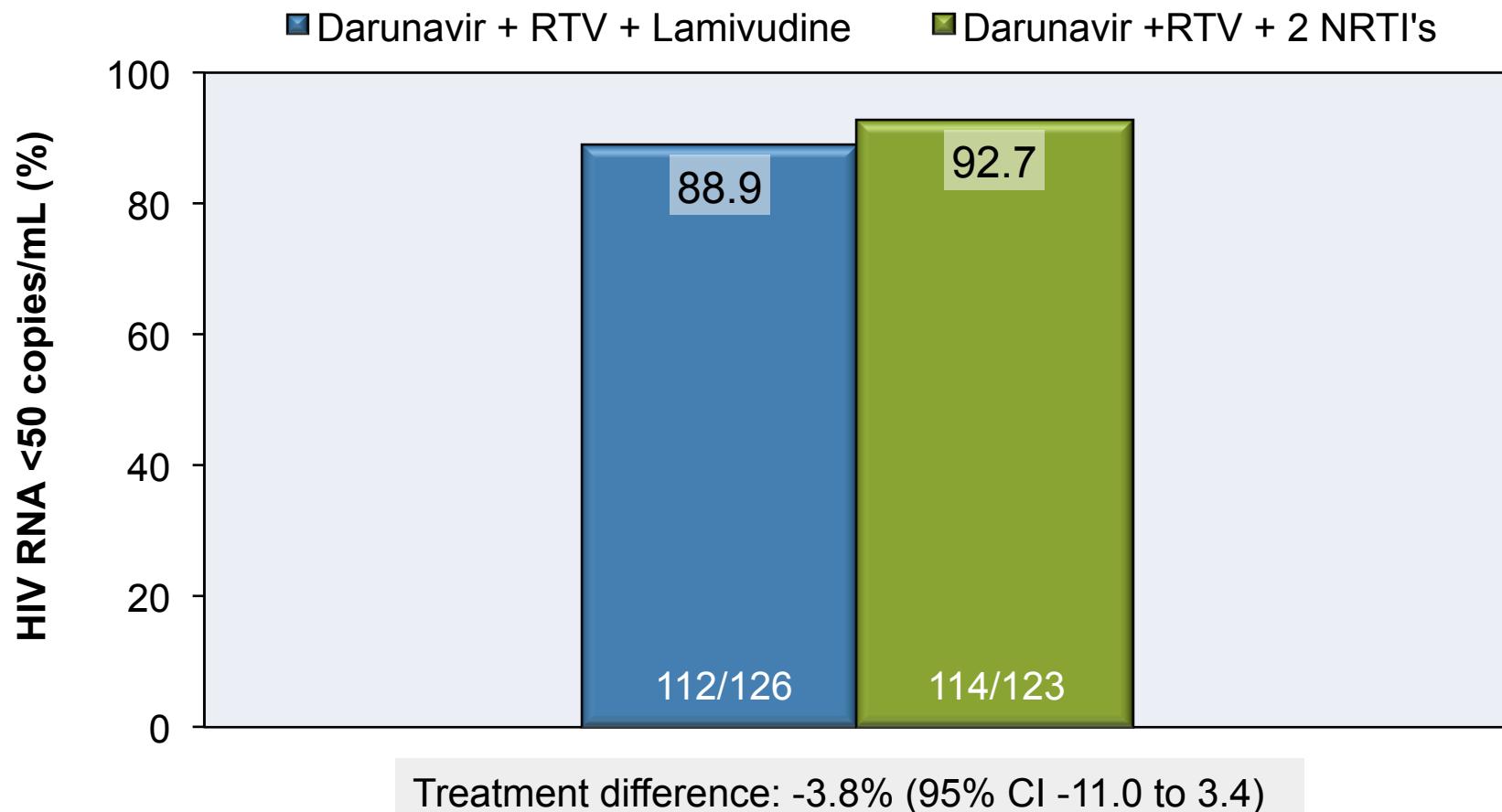
## DUAL-GESIDA: Baseline Characteristics

DUAL GESIDA: Baseline Characteristics		
	DRV + RTV + Lamivudine (n = 126)	Darunavir + RTV + 2 NRTIs (n = 123)
Male	107 (85%)	100 (81%)
Age (years, median, range)	44 (36-52)	43 (37-49)
IVDU	19 (15.1%)	15 (12.2%)
MSM	65 (51.6%)	72 (58.5%)
Heterosexual	34 (27%)	32 (26%)
Hepatitis C	32 (25.4%)	28 (22.8%)
Baseline CD4 (cells/ $\mu$ L)	596 (433-810)	568 (451-739)
Nadir CD4 (cells/ $\mu$ L)	253 (122-367)	240 (117-328)
Weeks since undetectable VL	79.5 (38-157)	113 (57-184)
Previous NRTI tenofovir	93 (74%)	93 (76%)
Previous NRTI abacavir	33 (26%)	30 (24%)

Source: Pulido F, et al. Clin Infect Dis. 2017;65:2112-8.

# Dual Maintenance ART with RTV-Boosted Darunavir + Lamivudine DUAL-GESIDA: Results

## Week 48 Virologic Response (ITT Analysis)



Source: Pulido F, et al. Clin Infect Dis. 2017;65:2112-8.

# Dual Maintenance ART with RTV-Boosted Darunavir + Lamivudine DUAL-GESIDA: Results

Treatment Emergent Adverse Events (AE's) in the DUAL GESIDA Study		
	DRV-r + Lamivudine (n = 126)	DRV-r + 2 NRTIs (n= 123)
$\geq 1$ AE	70%	76%
$\geq 1$ grade 2 to 4 AE	12%	15%
$\geq 1$ serious AE	5%	5%
Discontinuation due to AE	1%	2%
Deaths	0	0

Source: Pulido F, et al. Clin Infect Dis. 2017;65:2112-8.

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## DUAL GESIDA: Conclusion

**Conclusions:** “Dual therapy with darunavir/ritonavir and lamivudine demonstrated noninferior therapeutic efficacy and similar tolerability compared to triple therapy.”

# Acknowledgment

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