

DOR + 2 NRTIs vs. DRV + RTV + 2 NRTIs
DRIVE FORWARD

Doravirine + 2 NRTIs vs. Darunavir + Ritonavir + 2 NRTIs

DRIVE FORWARD: Design

DRIVE FORWARD: Study Design

- **Background:** Randomized, double-blind, phase 3 study evaluating the efficacy of doravirine versus ritonavir-boosted darunavir, both with 2NRTIs in antiretroviral-naïve adults with HIV.
- **Inclusion Criteria**
 - Age ≥ 18 years
 - Antiretroviral-naïve
 - HIV RNA $\geq 1,000$ copies/mL
 - No resistance to any study drug
 - Chronic HBV or HCV allowed
- **Regimens** (all once daily)
 - Doravirine (100 mg) + 2 NRTIs
 - Darunavir (800 mg) + Ritonavir (100 mg) + 2 NRTIs

Doravirine + 2 NRTIs
(n = 385)

Darunavir + RTV + 2 NRTIs
(n = 384)

Doravirine + 2 NRTIs vs. Darunavir + Ritonavir + 2 NRTIs

DRIVE FORWARD: Results

DRIVE FORWARD Baseline Characteristics

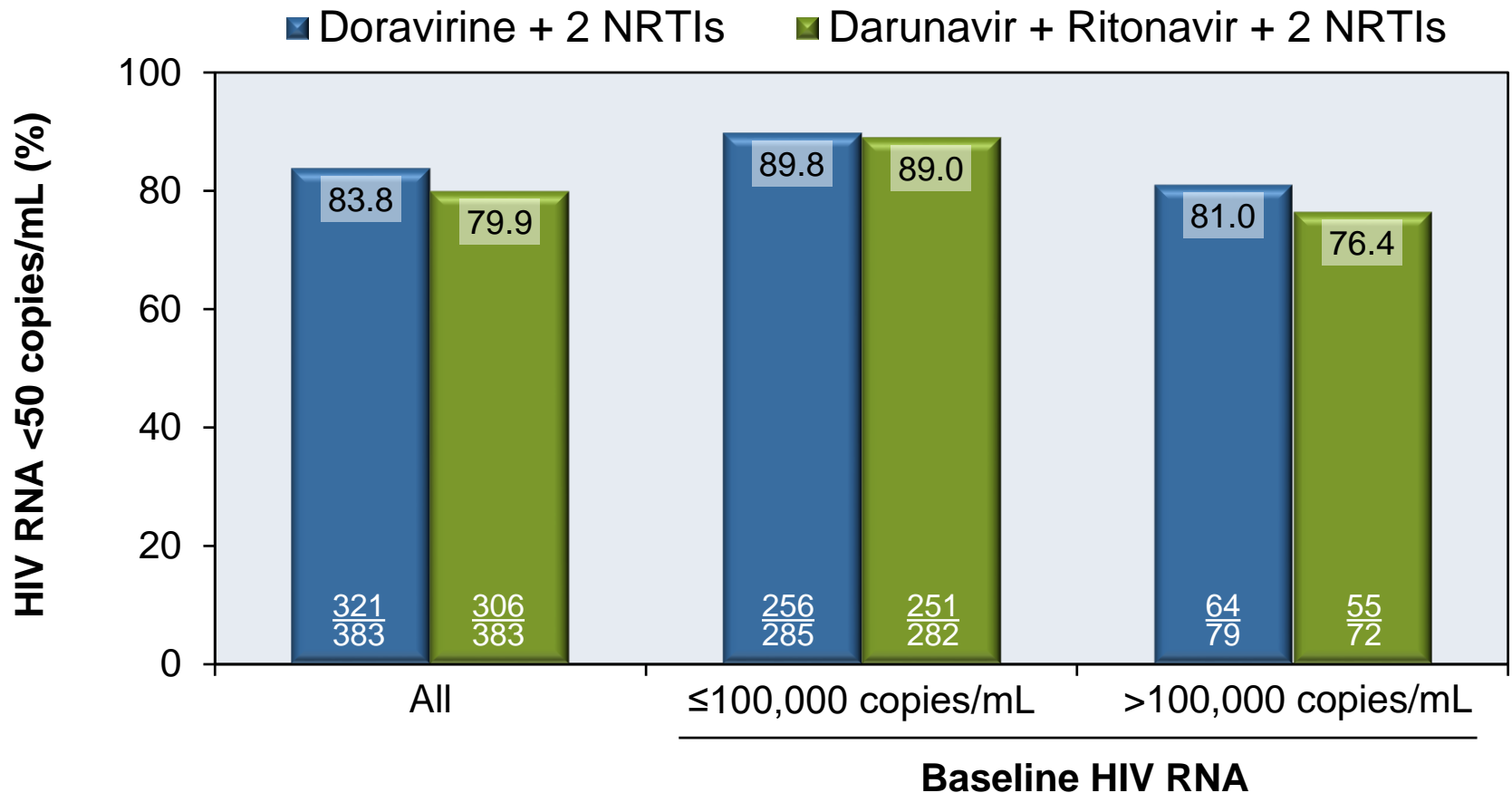
Characteristic	DOR + 2 NRTI's (n = 383)	DRV + RTV + 2 NRTI's (n = 383)
Age (years), median	34.8	35.7
Male, %	83.3	85.1
White, %	73.1	73.1
CD4 count (cells/mm ³), mean	432.6	411.9
HIV RNA, mean (log ₁₀)	4.4	4.4
HIV RNA >100,000 copies/mL, %	24.3	24.5
NRTI backbone TDF-FTC, %	86.9	87.5
NRTI backbone ABC-3TC, %	13.1	12.5

Source: Molina J-M, et al. Lancet HIV. 2018;5:e211-20.

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DRIVE FORWARD: 48 Week Results

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



Doravirine + 2 NRTIs vs. Darunavir + Ritonavir + 2 NRTIs

DRIVE FORWARD: 48 Week Results

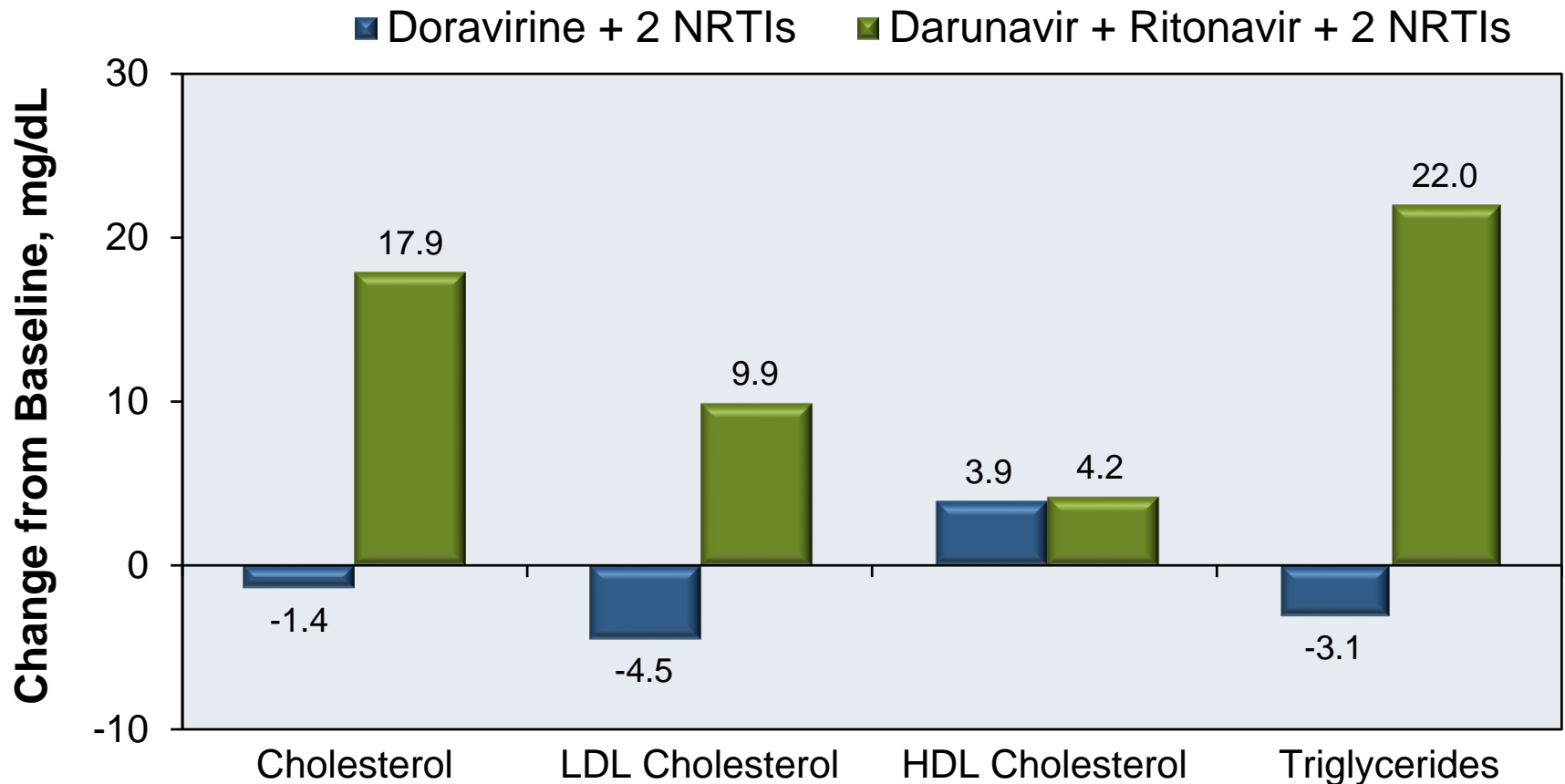
Treatment Related Adverse Events in DRIVE FORWARD Through Week 48		
	Doravirine + 2 NRTIs (n = 383)	DRV + RTV + 2 NRTIs (n = 383)
Any adverse drug-related event %	31	32
Discontinued due to drug-related AE, %	1	2
Upper abdominal pain, %	2	1
Diarrhea, %	5	13
Nausea, %	7	8
Headache, %	6	3
Dizziness, %	3	2
Fatigue, %	5	2
Rash, %	2	3
Neuropsychiatric, %	6	5

Source: Molina J-M, et al. Lancet HIV. 2018;5:e211-20.

Doravirine + 2 NRTIs vs. Darunavir + Ritonavir + 2 NRTIs

DRIVE FORWARD: Results

Change in Baseline Fasting Lipids at Week 48



Doravirine + 2 NRTIs vs. Darunavir + Ritonavir + 2 NRTIs

DRIVE FORWARD: Summary

Interpretation: “In treatment-naive adults with HIV-1 infection, doravirine combined with two NRTIs might offer a valuable treatment option for adults with previously untreated HIV-1 infection.”

Acknowledgment

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