

Dolutegravir + 2 NRTIs versus Darunavir + RTV + 2 NRTIs
FLAMINGO

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FLAMINGO: Study Design

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- Background:** Randomized, open label phase 3b study comparing dolutegravir to darunavir-ritonavir with fixed-dose NRTI backbone in antiretroviral-naïve persons with HIV.
- Inclusion Criteria (n = 484 analyzed)**
 - Antiretroviral-naïve
 - Age ≥ 18
 - HIV RNA $\geq 1,000$ copies/mL
 - No active class C conditions
 - No resistance to NRTIs or protease inhibitors
- Treatment Arms (once daily)**
 - Dolutegravir 50 mg + 2 NRTIs*
 - Darunavir 800 mg + Ritonavir 100 mg + 2 NRTIs*

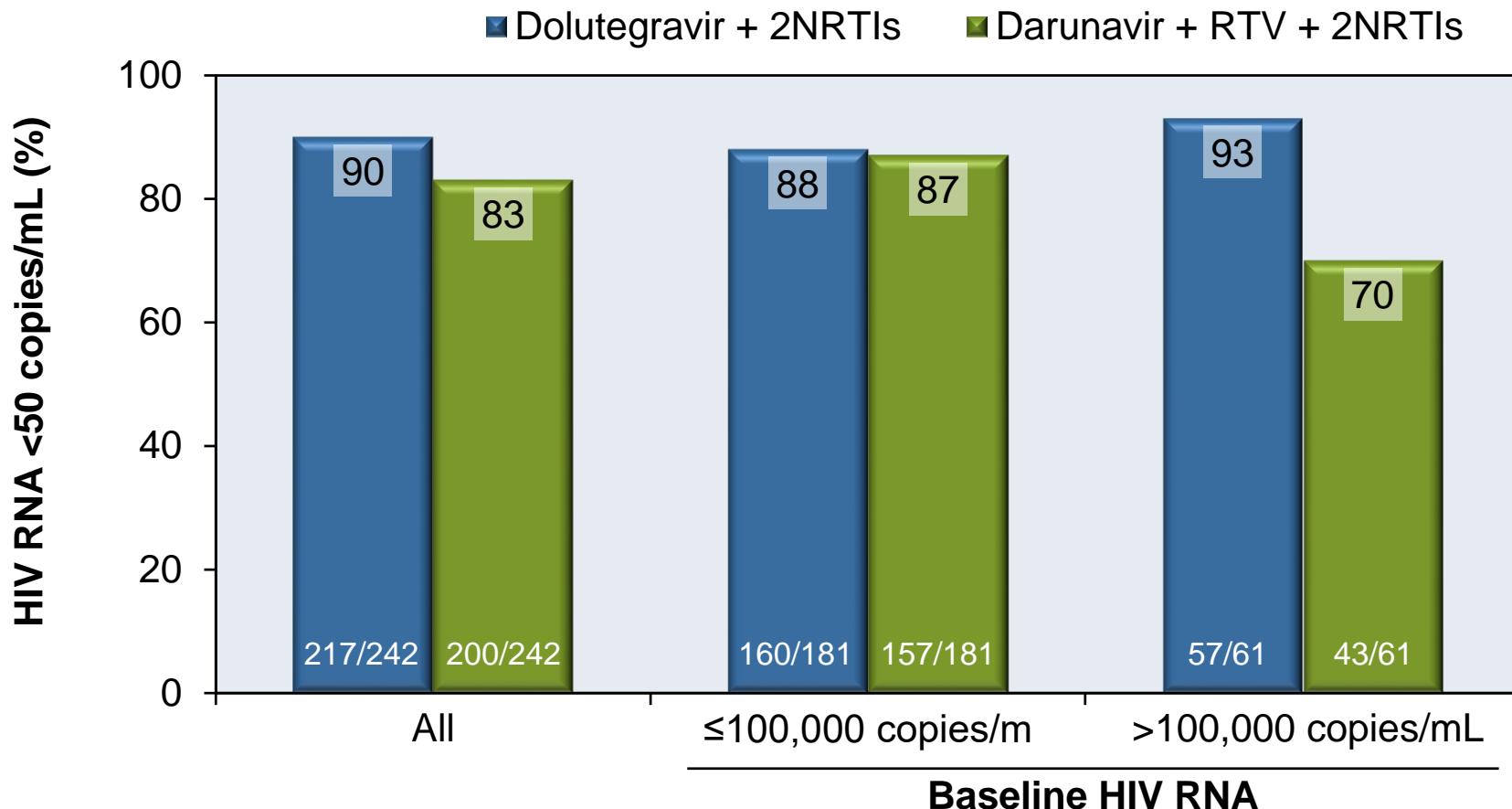
**Dolutegravir +
TDF-FTC or ABC-3TC
(n = 242)**

**Darunavir + Ritonavir +
TDF-FTC or ABC-3TC
(n = 242)**

*2 NRTIs = tenofovir-emtricitabine or abacavir-lamivudine (with negative HLA-B*5701 testing).

Dolutegravir + 2 NRTIs versus Darunavir + RTV + 2 NRTIs FLAMINGO: Results

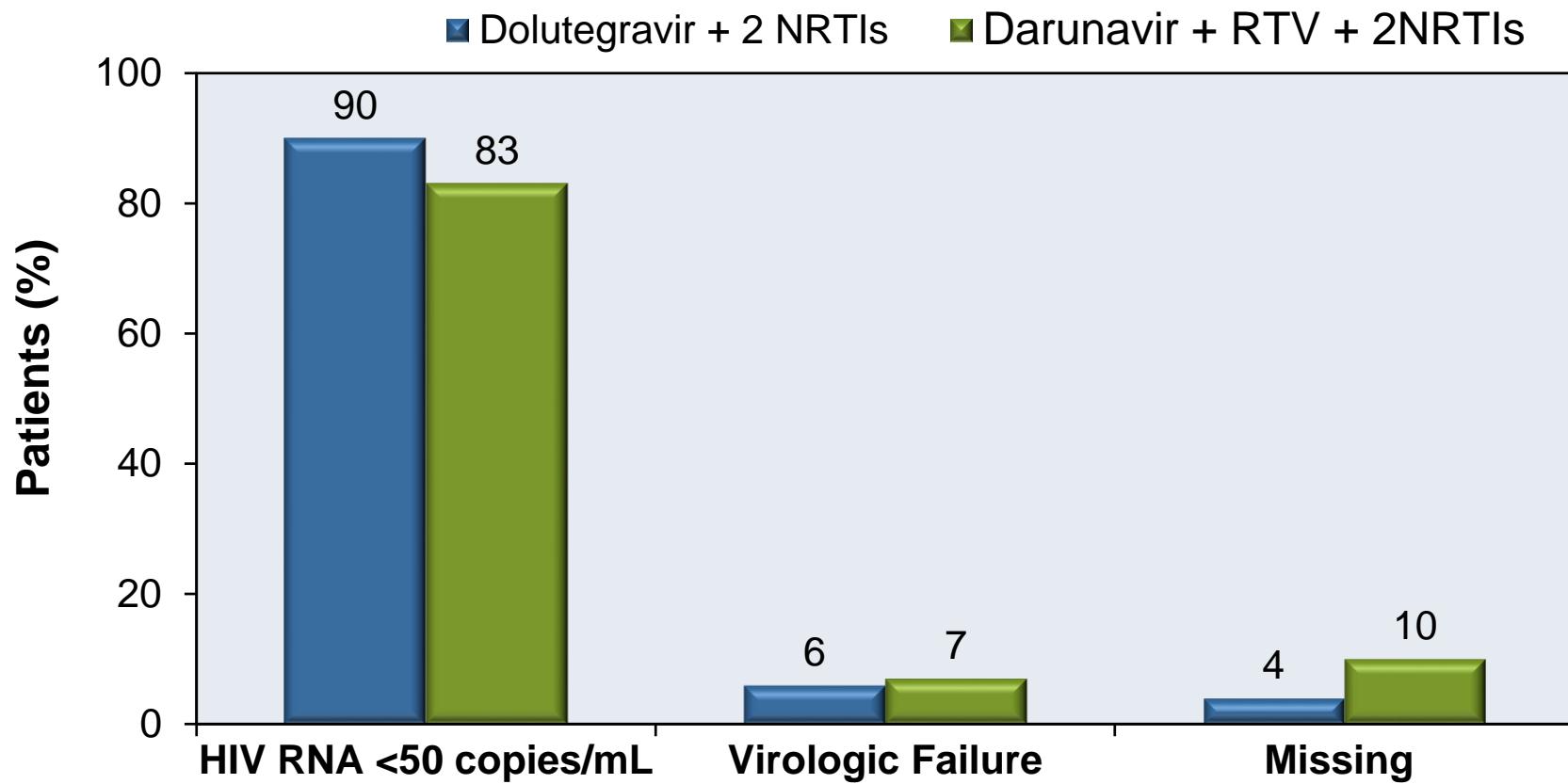
Week 48 Virologic Response, by Baseline HIV RNA Level



Source: Clotet B, et al. Lancet. 2014;383:2222-31.

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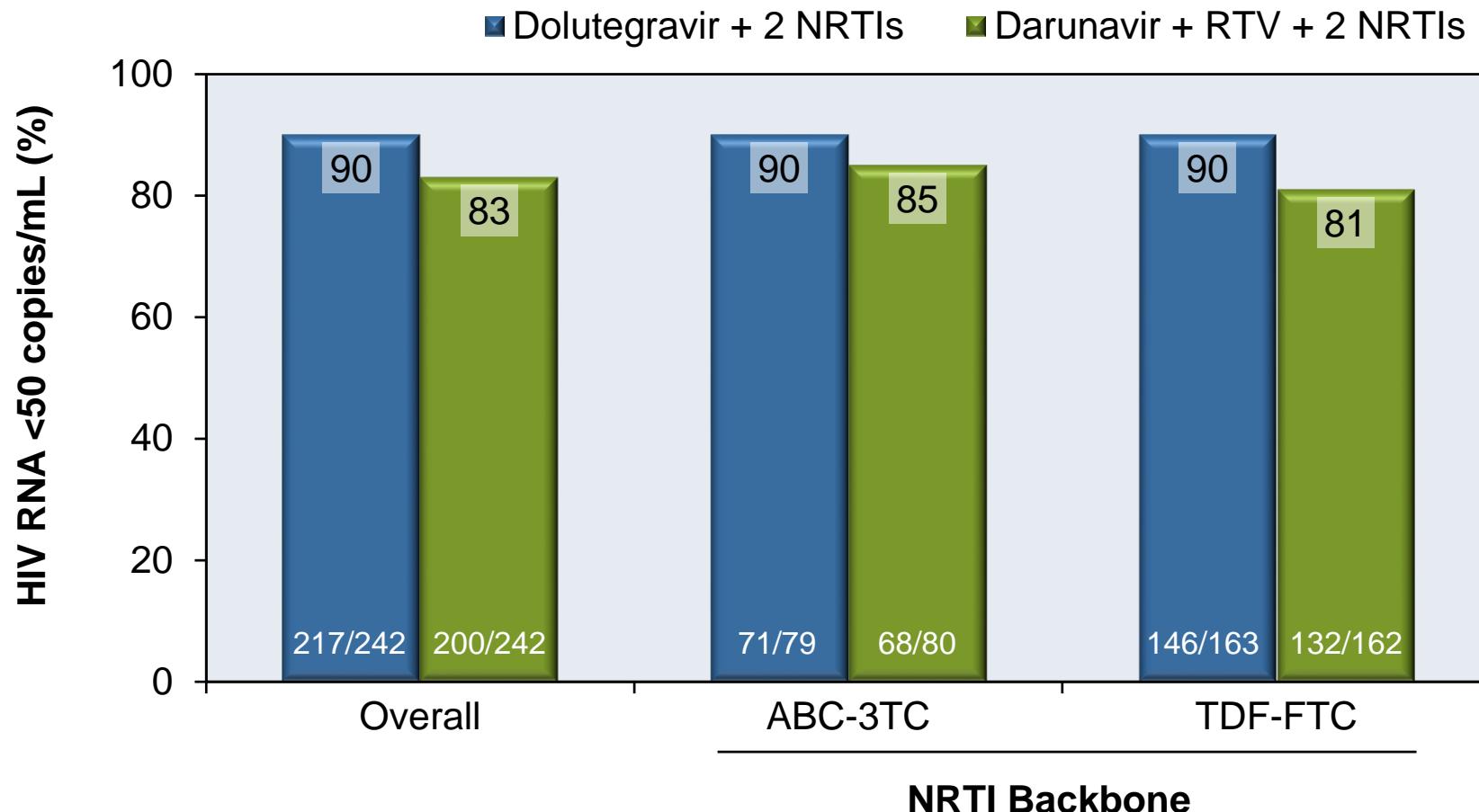
48 Week Virologic Outcomes (Modified Intent-to-Treat Analysis)



Source: Clotet B, et al. Lancet. 2014;383:2222-31.

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Week 48 Virologic Response, by Background Dual NRTI Therapy



Source: Clotet B, et al. Lancet. 2014;383:2222-31.

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FLAMINGO: Common Adverse Events

Treatment Emergent Adverse Events in $\geq 5\%$ of Subjects in Either Arm		
	DTG + 2 NRTIs (n = 242)	DRV + RTV + 2 NRTIs (n= 242)
Dizziness	17%	29%
Nausea	16%	18%
Headache	15%	10%
Nasopharyngitis	9%	8%
Upper respiratory infection	5%	10%
Insomnia	7%	6%
Cough	5%	7%
Vomiting	6%	6%
Fatigue	6%	5%

Source: Clotet B, et al. Lancet. 2014;383:2222-31.

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FLAMINGO: Common Adverse Events (continued)

Treatment Emergent Adverse Events in $\geq 5\%$ of Subjects in Either Arm		
	DTG + 2 NRTIs (n = 242)	DRV + RTV + 2 NRTIs (n = 242)
Pyrexia	5%	6%
Dizziness	6%	5%
Rash	4%	6%
Back Pain	4%	5%
Pharyngitis	3%	5%
Bronchitis	2%	5%
Sinusitis	2%	5%
Depression	5%	2%
Arthralgia	2%	5%

Source: Clotet B, et al. Lancet. 2014;383:2222-31.

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FLAMINGO: Conclusions

Interpretation: “Once-daily dolutegravir was superior to once-daily darunavir plus ritonavir. Once-daily dolutegravir in combination with fixed-dose NRTIs represents an effective new treatment option for HIV-1-infected, treatment-naive patients.”

Acknowledgment

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