

Dolutegravir vs. Raltegravir
SPRING-2 Study

Dolutegravir versus Raltegravir

SPRING-2: Design

Study Design: SPRING-2

- **Background:** Randomized, double-blind study, phase 3 trial comparing dolutegravir versus raltegravir, both with 2NRTI backbone for persons with HIV.
- **Inclusion Criteria (n = 822)**
 - Antiretroviral-naïve patients
 - Age ≥ 18 years
 - HIV RNA $\geq 1,000$ copies/mL
 - No active CDC AIDS condition
- **Treatment Arms**
 - Dolutegravir + 2NRTIs
 - Raltegravir + 2NRTIs
 - Fixed dose 2NRTIs* = TDF-FTC or ABC-3TC

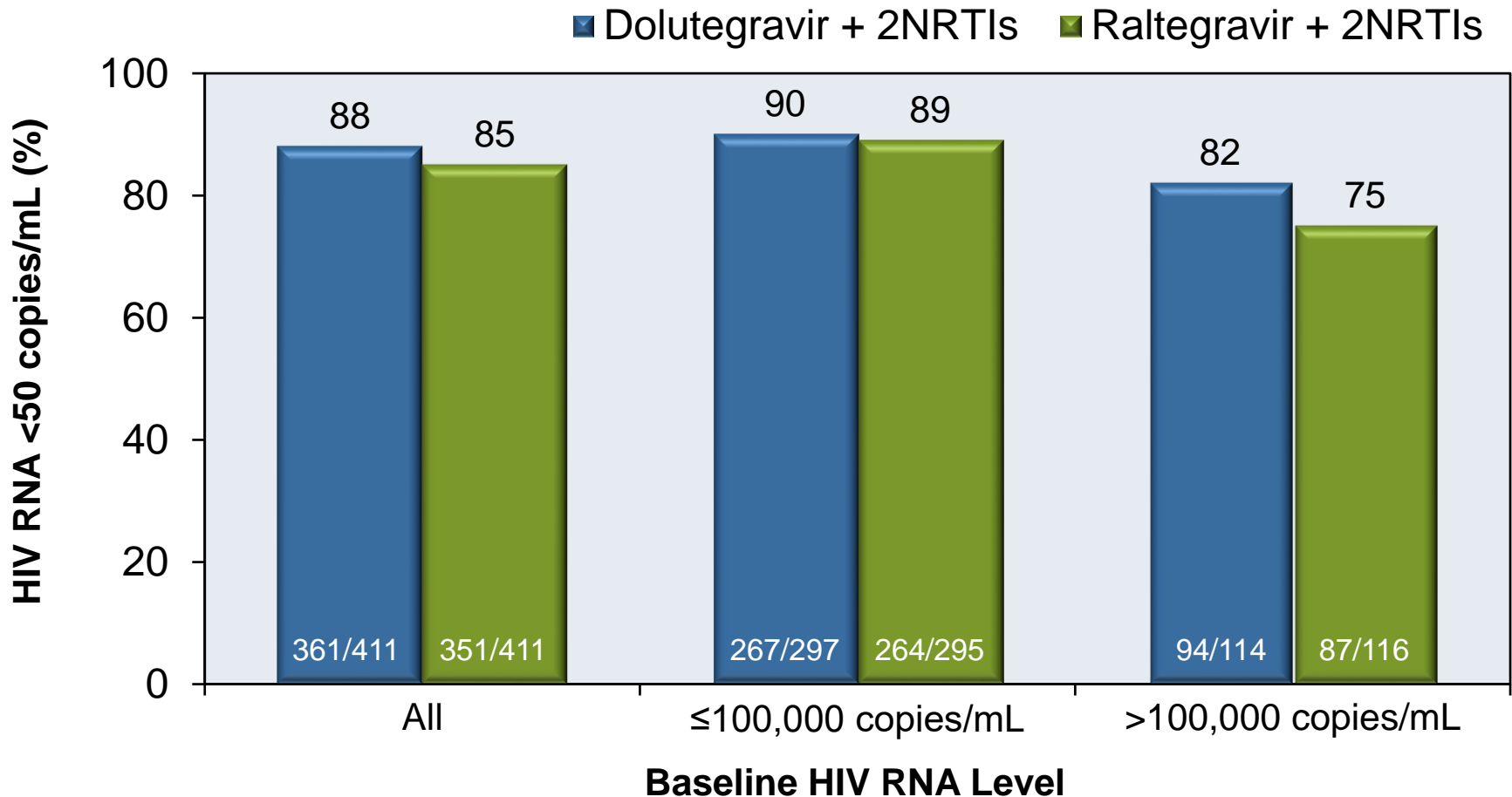
Dolutegravir: 50 mg QD
Fixed-dose NRTI backbone*
(n = 411)

Raltegravir: 400 mg BID
Fixed-dose NRTI backbone*
(n = 411)

Dolutegravir versus Raltegravir

SPRING-2: Results

Week 48: Virologic Response, by Baseline HIV RNA

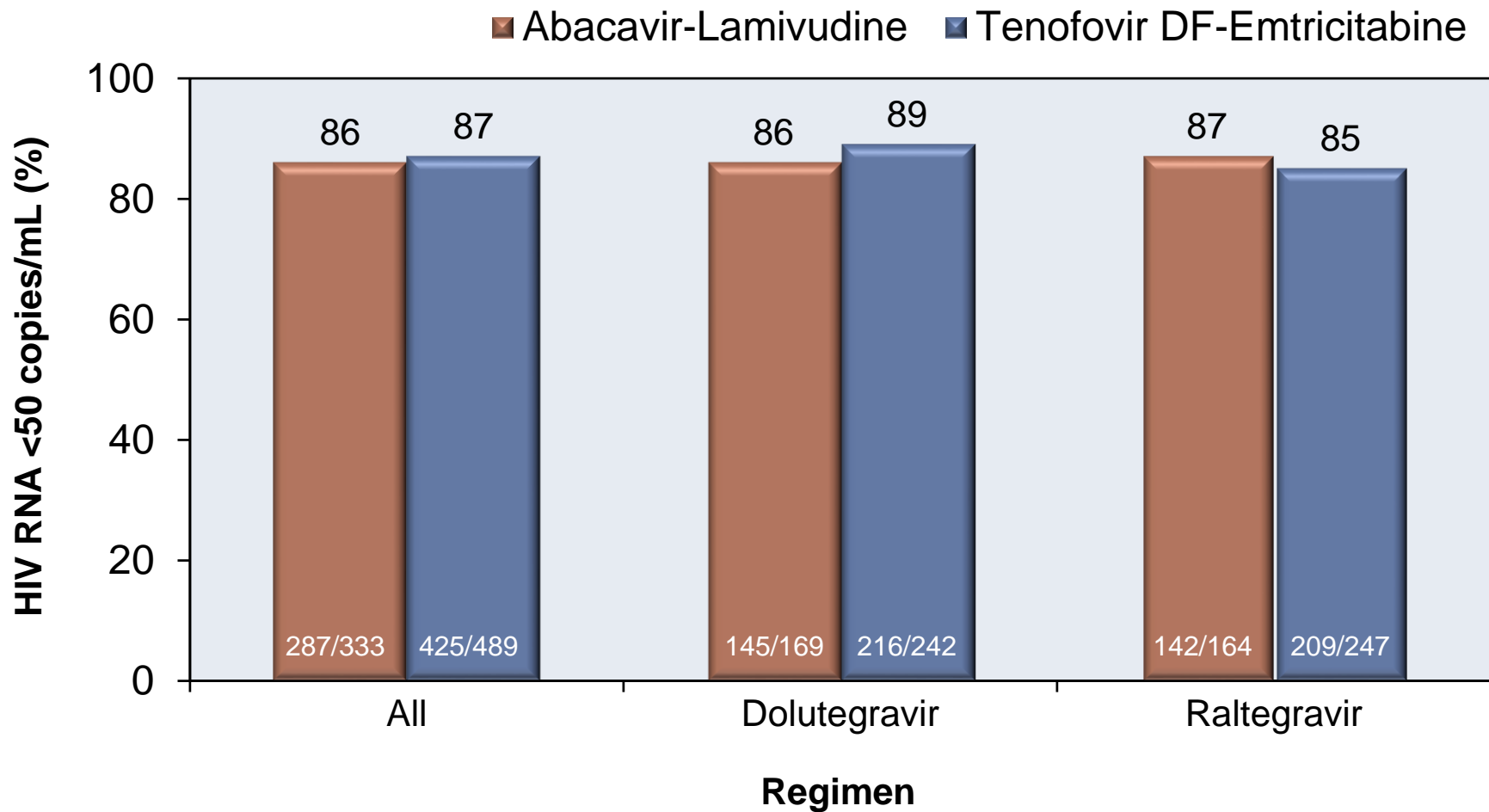


Source: Raffi F, et al. Lancet. 2013;381:735-43.

Dolutegravir versus Raltegravir

SPRING-2: Results

Week 48: Virologic Response, by NRTI Component



Source: Raffi F, et al. Lancet. 2013;381:735-43.

Dolutegravir versus Raltegravir

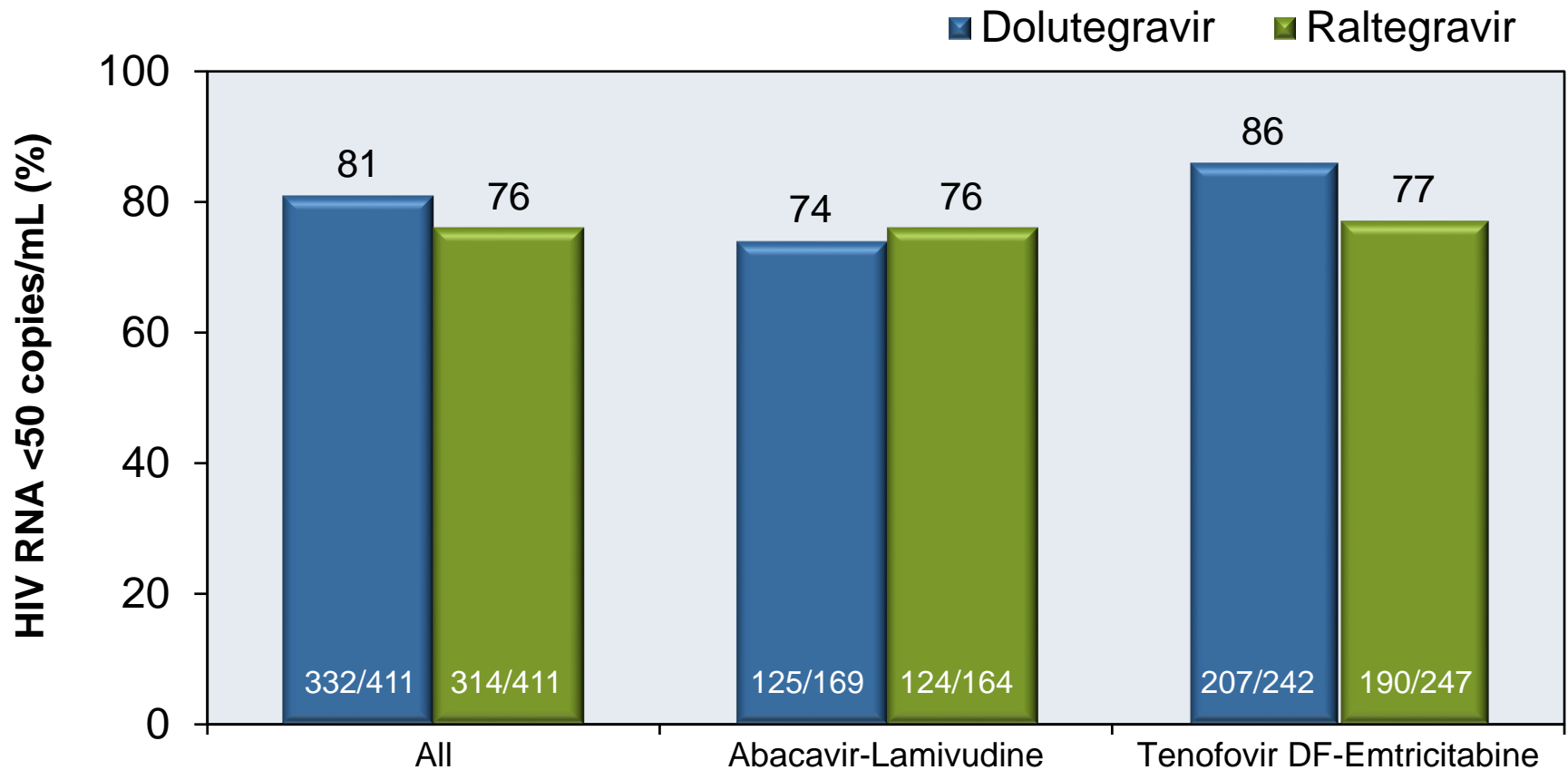
SPRING-2: Conclusions

Interpretation: “The non-inferior efficacy and similar safety profile of dolutegravir compared with raltegravir means that if approved, combination treatment with once-daily dolutegravir and fixed-dose nucleoside reverse transcriptase inhibitors would be an effective new option for treatment of HIV-1 in treatment-naive patients.”

Dolutegravir vs. Raltegravir
SPRING-2 Study: Week 96 Data

Dolutegravir + 2NRTIs versus Raltegravir + 2NRTIs SPRING-2 (Week 96): Results

Week 96 Virologic Response: Background Dual NRTI Therapy



Source: Raffi F, et al. Lancet Infect Dis. 2013;13:927-35.

Dolutegravir versus Raltegravir SPRING-2 (Week 96): Conclusions

Interpretation: “At week 96, once-daily dolutegravir was non-inferior to twice-daily raltegravir in treatment-naive, patients with HIV-1. Once-daily dosing without requirement for a pharmacokinetic booster makes dolutegravir-based therapy an attractive treatment option for HIV-1-infected treatment-naive patients.”

Acknowledgment

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