

Darunavir/r Monotherapy versus Triple Therapy
MONET Trial

Darunavir/r Monotherapy versus Triple Therapy

MONET: Study Design

Study Design: MONET

- **Background:** Randomized, controlled, open-label, phase 3b trial evaluate noninferiority of darunavir + ritonavir (monotherapy) versus darunavir + ritonavir + 2NRTIs (triple therapy) in virologically suppressed patients
- **Inclusion Criteria (n = 256)**
 - HIV RNA <50 copies/mL x 24 weeks on 3-drug Rx
 - CD4 count >200 cells/mm³
 - CD4 count nadir >100 cells/mm³
 - No PI resistance or history of virologic failure
- **Treatment Arms**
 - Darunavir 800 mg QD + RTV 100 mg QD
 - Darunavir 800 mg QD + RTV 100 mg QD + 2 NRTIs

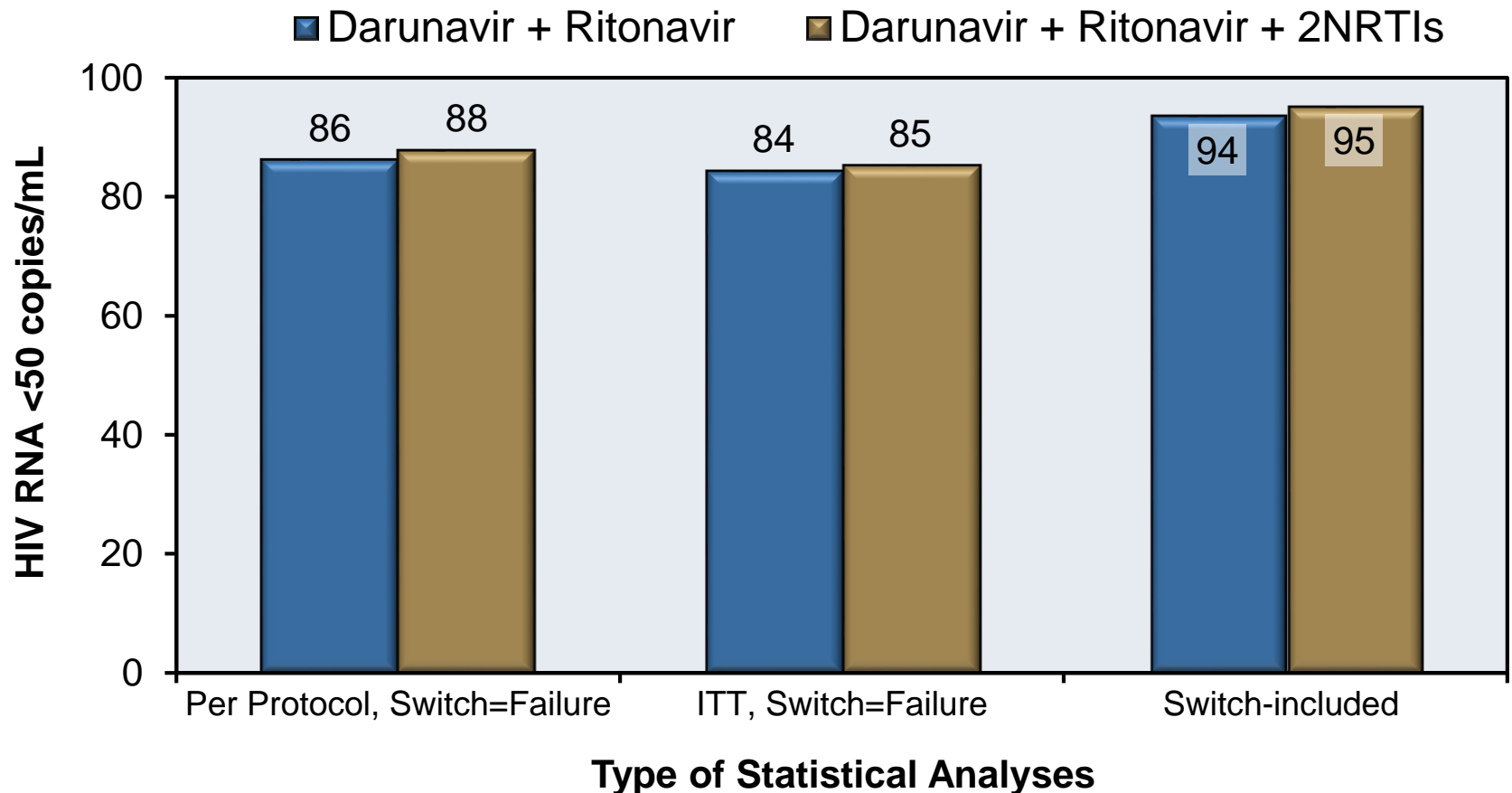
**Darunavir 800 mg QD
+ Ritonavir 100 mg QD**
(n = 127)

**Darunavir 800 mg QD
+ Ritonavir 100 mg QD
+ 2 NRTIs**
(n = 129)

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MONET: Result

Week 48: Virologic Response, by Statistical Efficacy Analyses



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MONET: Result

Summary of Genotypic Resistance Detected Post-Randomization		
	DRV + RTV (n = 127)	DRV + RTV + 2NRTIs (n = 129)
≥1 HIV RNA result ≥50 copies/mL post-baseline, n (%)	39 (30.7%)	31 (24%)
Number of HIV RNA results ≥50 copies/mL, n	89	47
Number of genotypes performed, n	74	42
Successful genotypes, n (%)	40 (54.1%)	19 (45.2%)
≥1 successful genotype, n (%)	24 (18.9%)	14 (10.9%)
No primary PI, DRV, NRTI or M184V mutations, n (%)	23 (95.8%)	13 (92.9%)
≥1 IAS–USA primary PI mutations, n (%)	1 (4.2%)	1(7.1%)
≥1 DRV mutations, n (%)	1 (4.2%)	0
M184V mutation, n (%)	0	1(7.1%)
Other NRTI mutations, n (%)	0	0

Source: Pulido F, et al. *Antivir Ther.* 2011;16:59-65.

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MONET: Conclusions

Conclusions: “In this study for patients with HIV RNA less than 50 copies/ml on other antiretrovirals at baseline, switching to DRV/r monotherapy showed noninferior efficacy versus triple antiretroviral therapy.”

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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