Darunavir/r Monotherapy versus Triple Therapy

PROTEA Trial

Darunavir/r Monotherapy versus Triple Therapy
PROTEA: Study Design

Study Design: PROTEA Study

- **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 = 273)**
  - HIV RNA <50 copies/mL x 24 weeks on 3-drug ART
  - CD4 count >200 cells/mm^3
  - CD4 count nadir >100 cells/mm^3
  - 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 = 137)

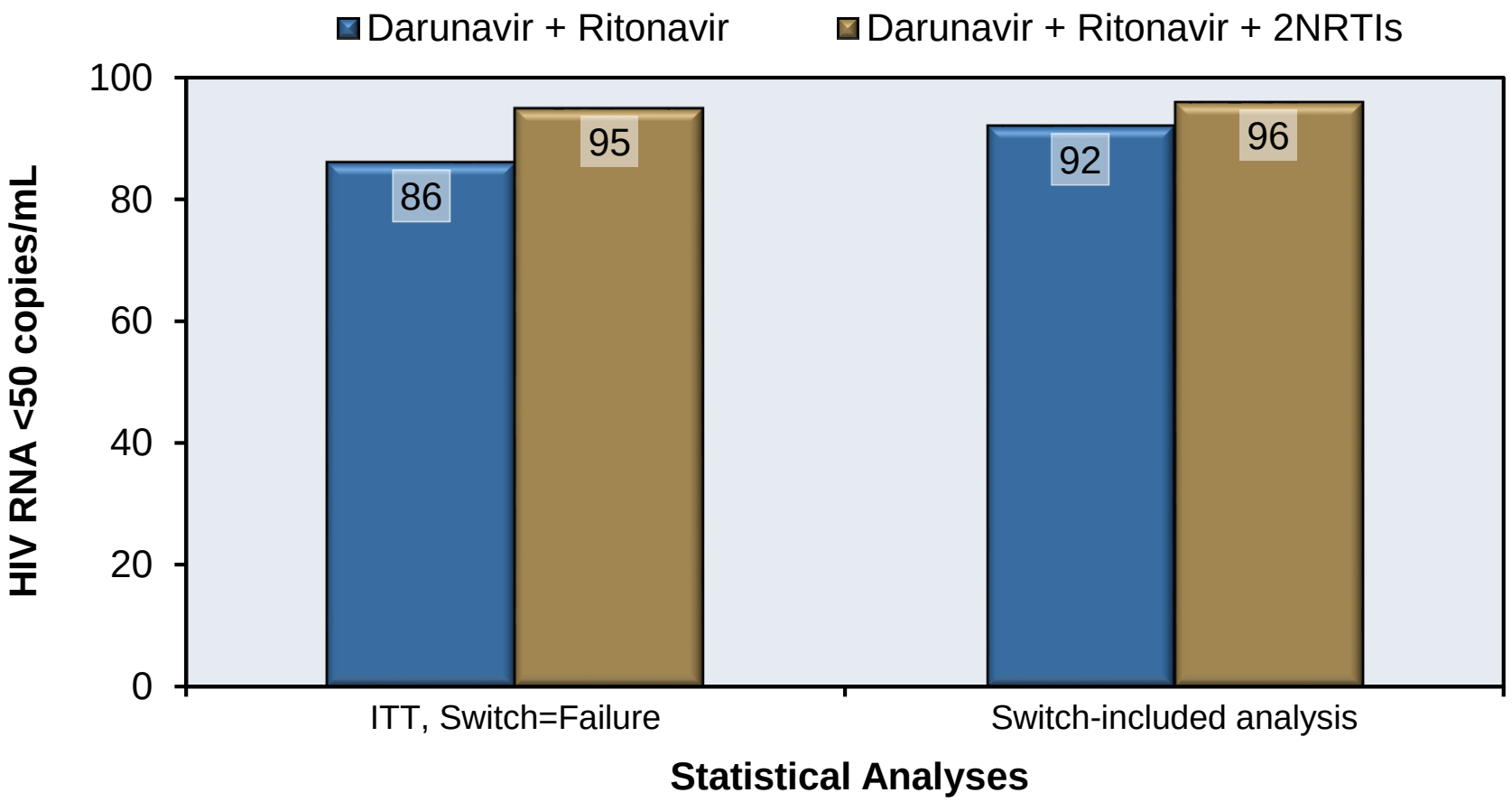
Darunavir 800 mg QD + Ritonavir 100 mg QD + 2 NRTIs (n = 136)

*Both arms: 4-week run-in with DRV + RTV + 2 NRTIs

Source: Antinori A, et al. J Int AIDS Soc. 2014;17:19525.

Darunavir/r Monotherapy versus Triple Therapy
PROTEA: Result

Week 48: Virologic Response, by Statistical Efficacy Analyses



Source: Antinori A, et al. J Int AIDS Soc. 2014;17:19525.

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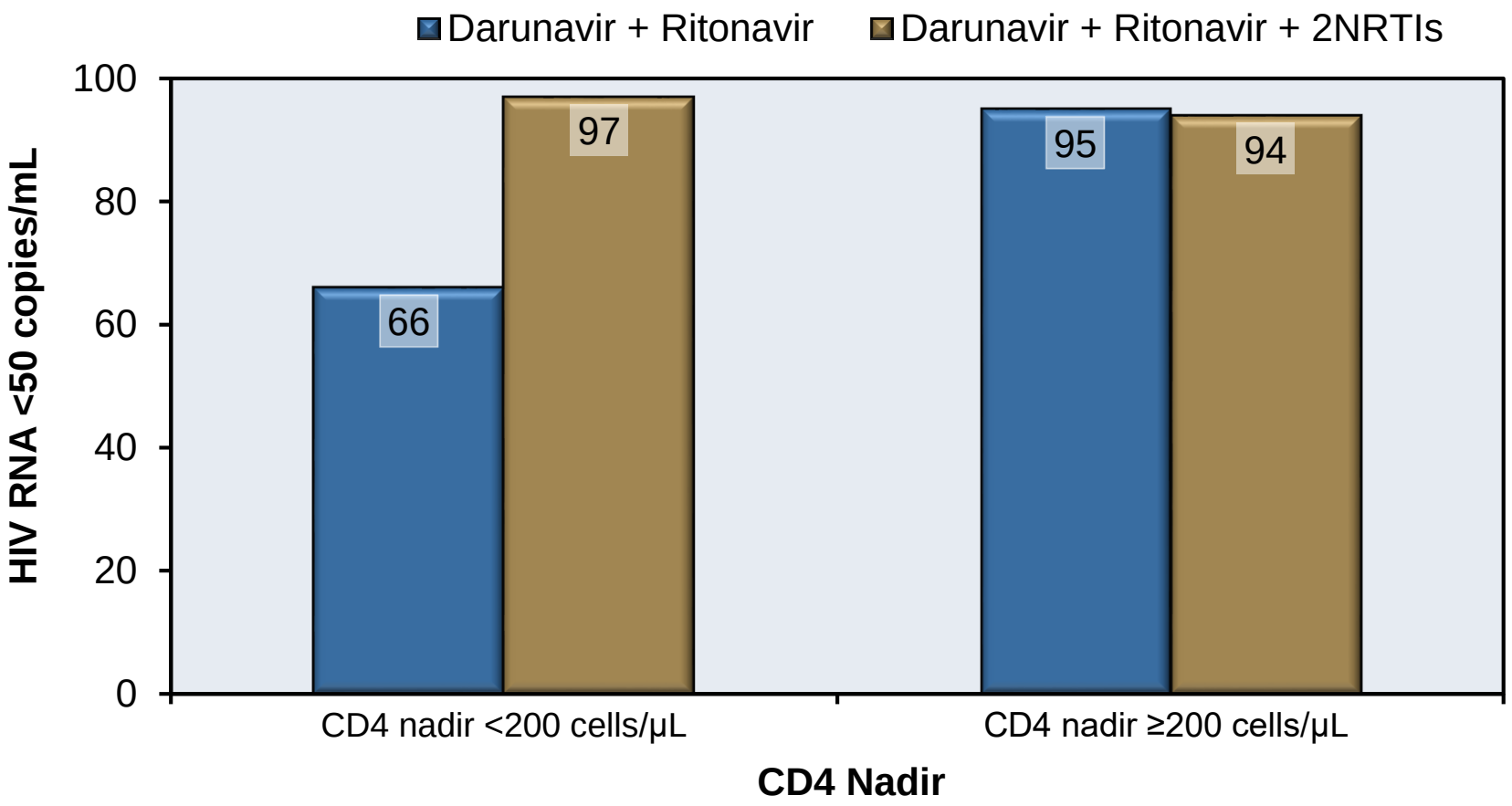
PROTEA: Result

Week 48: Virologic Response, by Nadir CD4 Count



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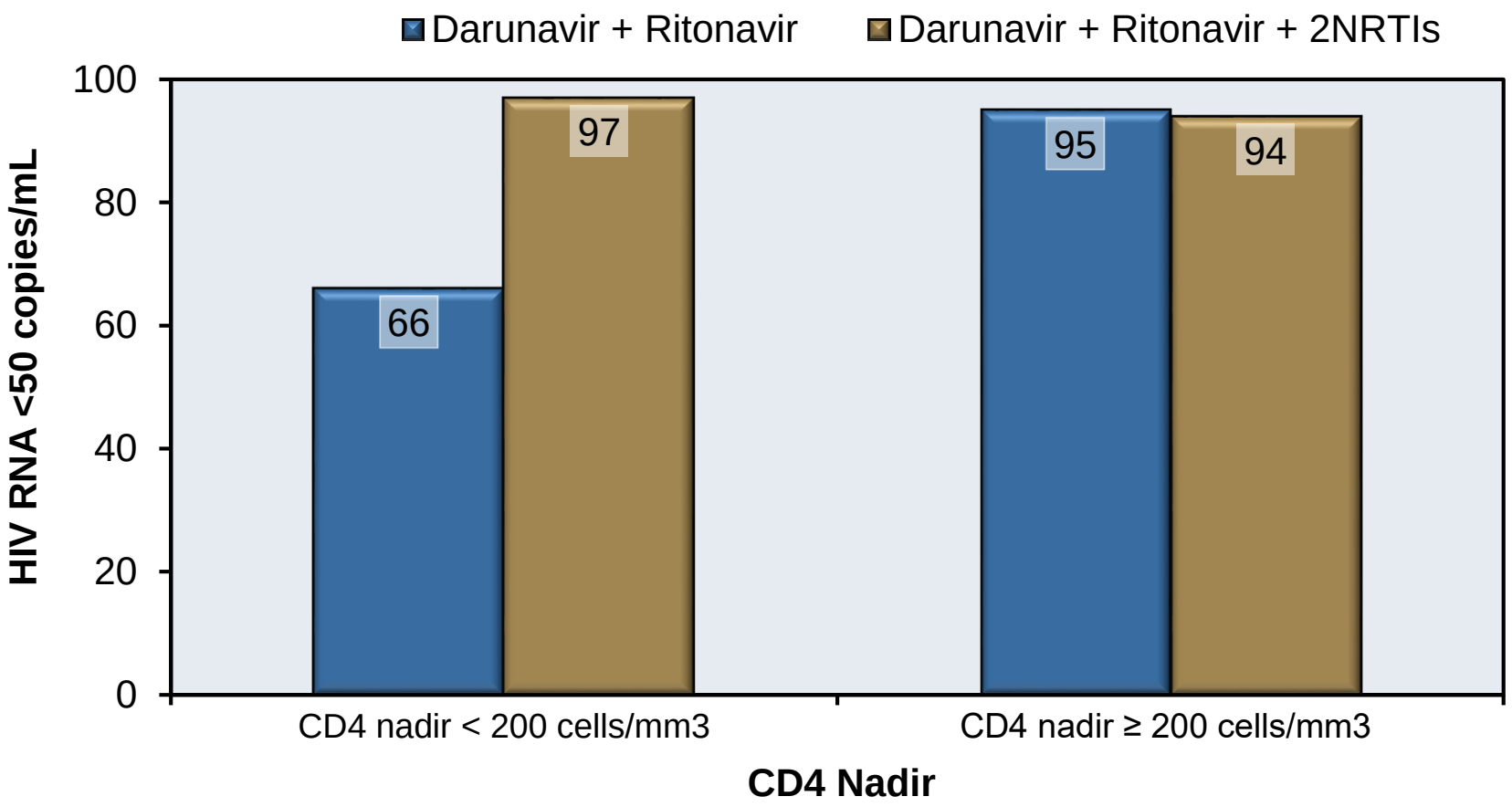
PROTEA: Result

Week 48: Virologic Response, by Nadir CD4 Count



Source: Antinori A, et al. J Int AIDS Soc. 2014;17:19525.

Darunavir/r Monotherapy versus Triple Therapy
PROTEA: Conclusions

Conclusions: “In this study for patients with HIV-1 RNA < 50 copies/mL at baseline, switching to DRV/r monotherapy showed lower efficacy versus triple antiretroviral therapy at Week 48 in the primary switch equals failure analysis (86% versus 95%). However, this lower efficacy was seen mainly in patients with CD4 nadir levels below 200 cells/µL. There was no development of PI resistance.”

Source: Antinori A, et al. J Int AIDS Soc. 2014;17:19525.

Acknowledgment

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The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

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AETC AIDS Education & Training Center Program
National Coordinating Resource Center