

Darunavir/r Monotherapy versus Triple Therapy
MONOI-ANRS 136 Trial

Darunavir/r Monotherapy versus Triple Therapy

MONOI-ANRS 136: Study Design

Study Design: MONOI-ANRS 136

- **Background:** Randomized, open-label, phase 3 trial to evaluate noninferiority of darunavir + ritonavir (monotherapy) versus darunavir + ritonavir + 2NRTIs (triple therapy) in virologically suppressed patients
- **Inclusion Criteria (n = 226)**
 - Age ≥ 18
 - HIV RNA < 400 copies/mL x 18 months on 3-drug Rx
 - HIV RNA < 50 copies/mL at screening
 - CD4 nadir > 50 cells/mm³
 - No history of virologic failure on PI-based regimen
- **Treatment Arms***
 - Darunavir 600 mg BID + RTV 100 mg BID
 - Darunavir 600 mg BID + RTV 100 mg BID + 2NRTIs

**Darunavir 600 mg BID +
Ritonavir 100 mg BID**
(n = 112)

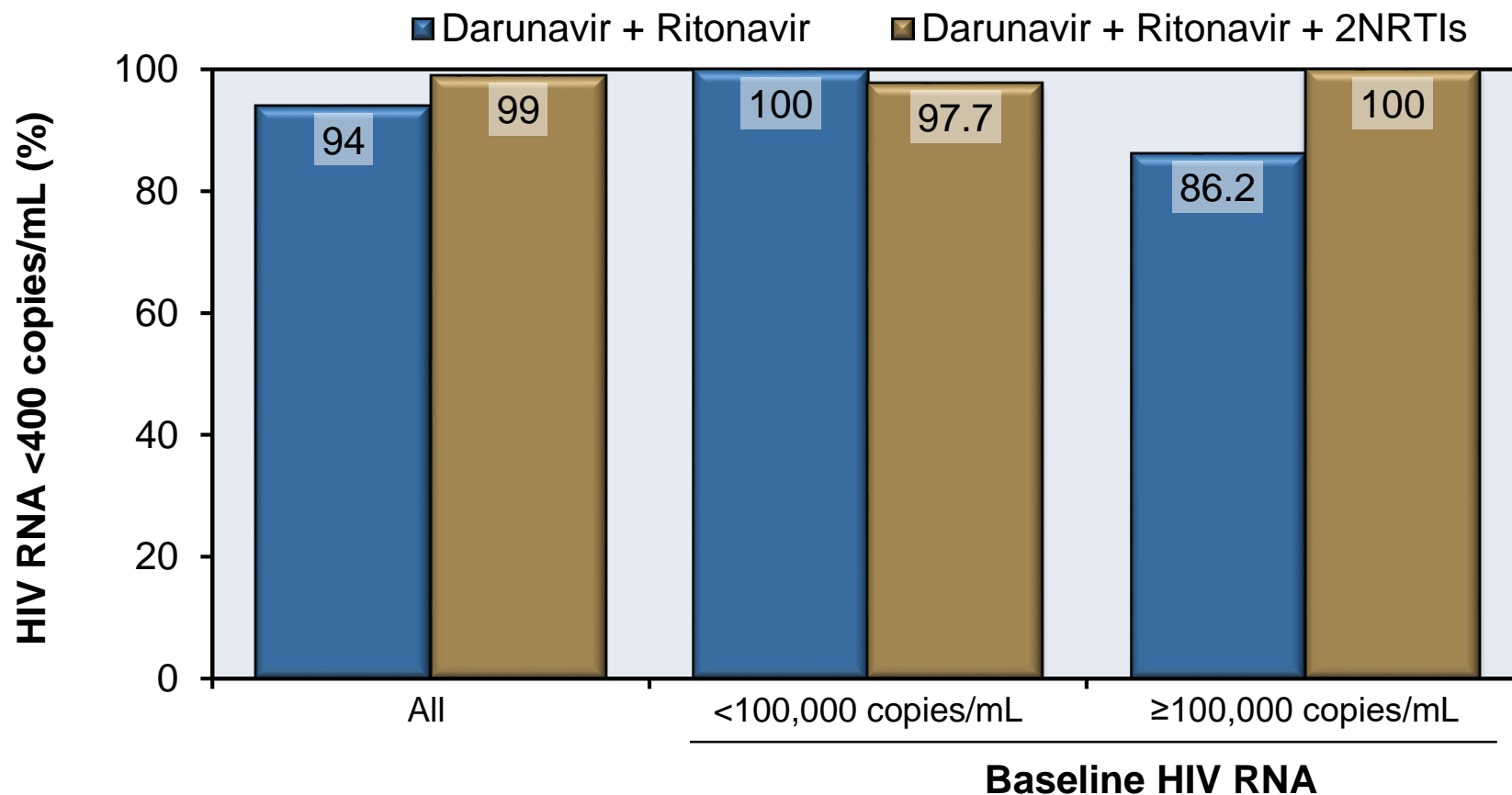
**Darunavir 600 mg BID +
Ritonavir 100 mg BID +
2 NRTIs**
(n = 113)

*Both arms: 8-week run-in with DRV/r + 2 NRTIs

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MONOI-ANRS 136: Result

Week 48: HIV RNA <400 copies/mL, by Baseline HIV RNA (Per Protocol Analysis)



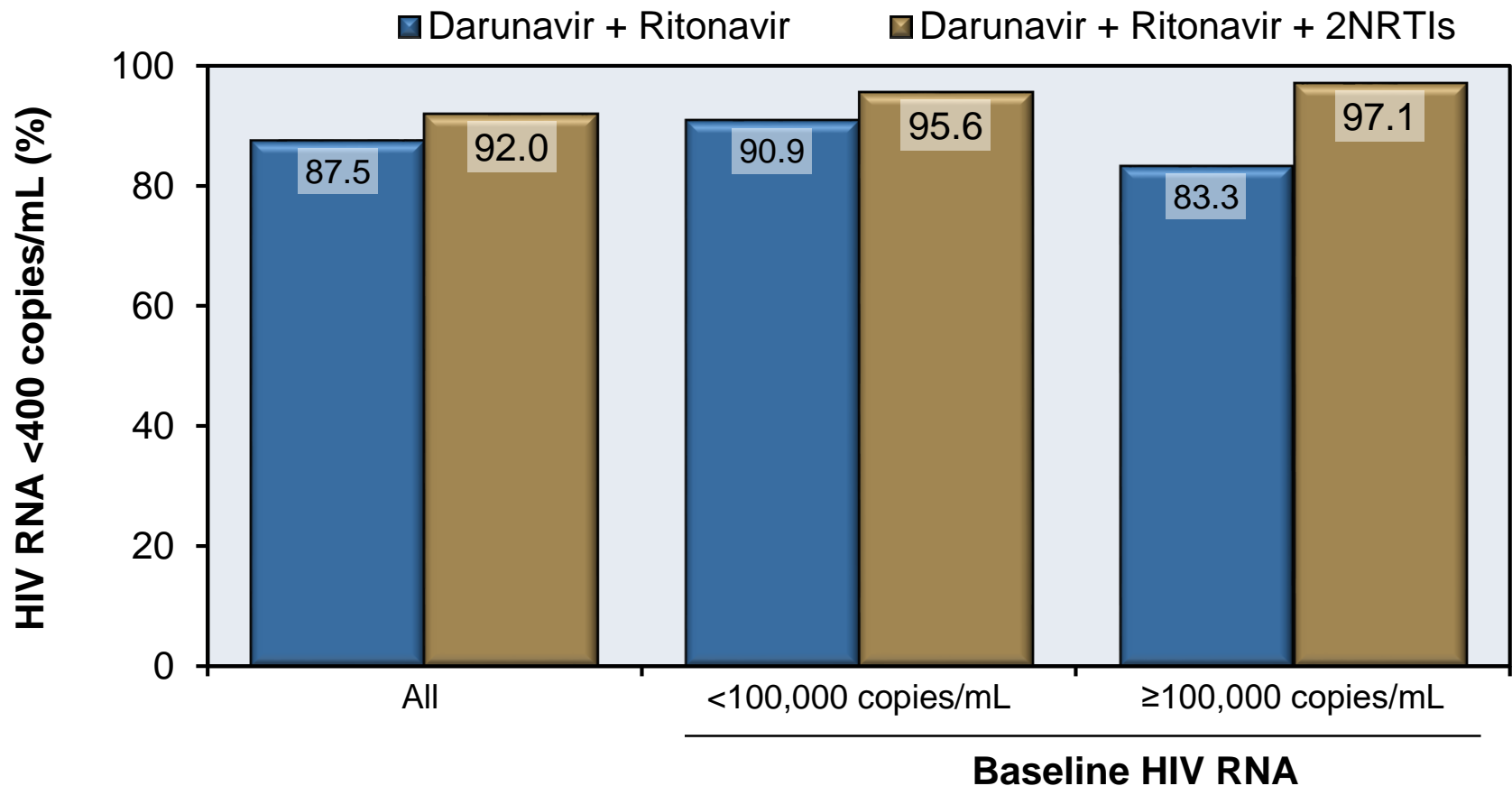
Treatment failure = virologic failure, treatment modification/discontinuation, withdrawal

Source: Katlama C, et al. AIDS. 2010;24:2365-74.

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MONOI-ANRS 136: Result

Week 48: HIV RNA <400 copies/mL, by Baseline HIV RNA (ITT Analysis)



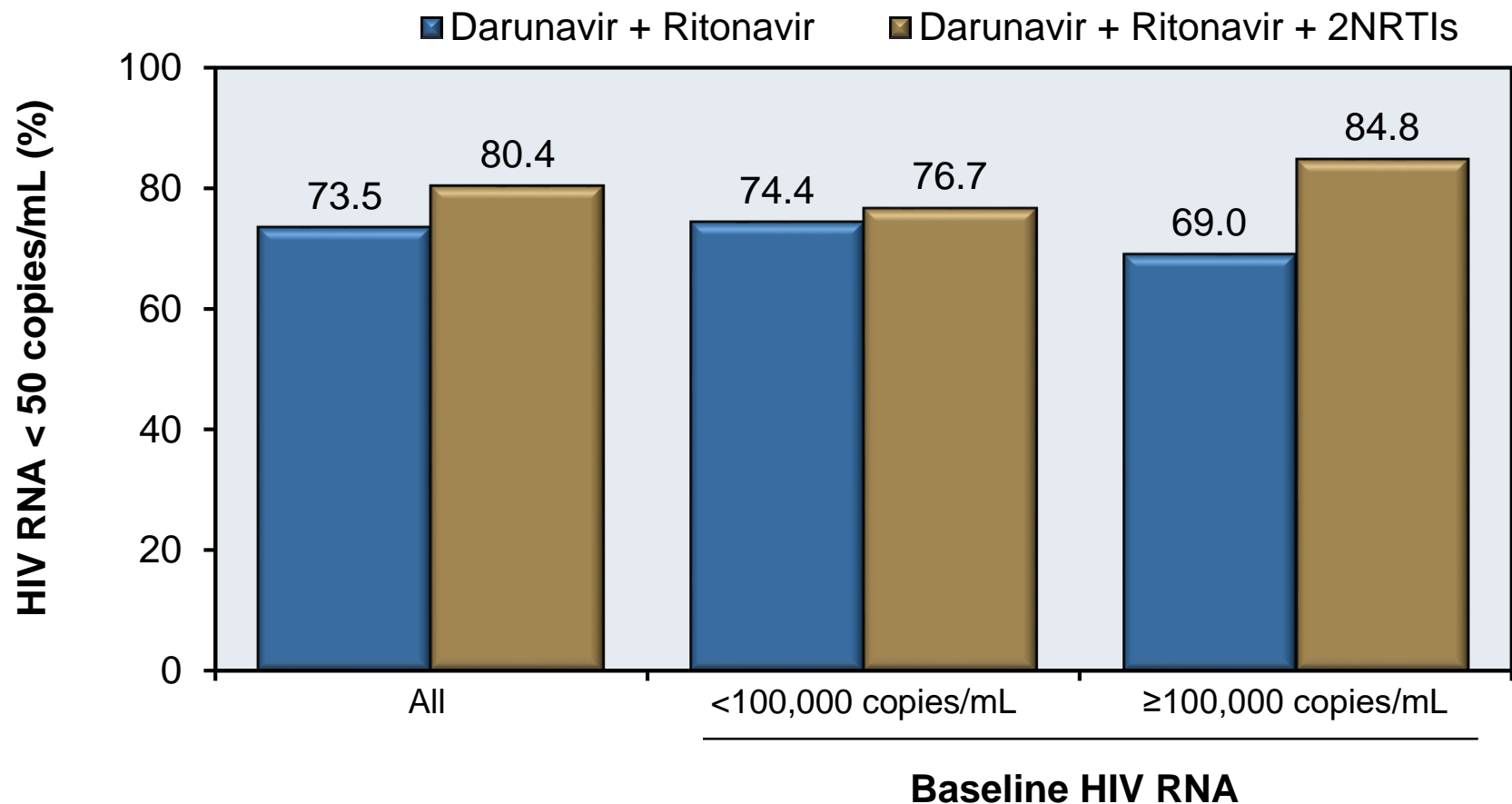
Treatment failure = virologic failure, treatment modification/discontinuation, withdrawal

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MONOI-ANRS 136: Result

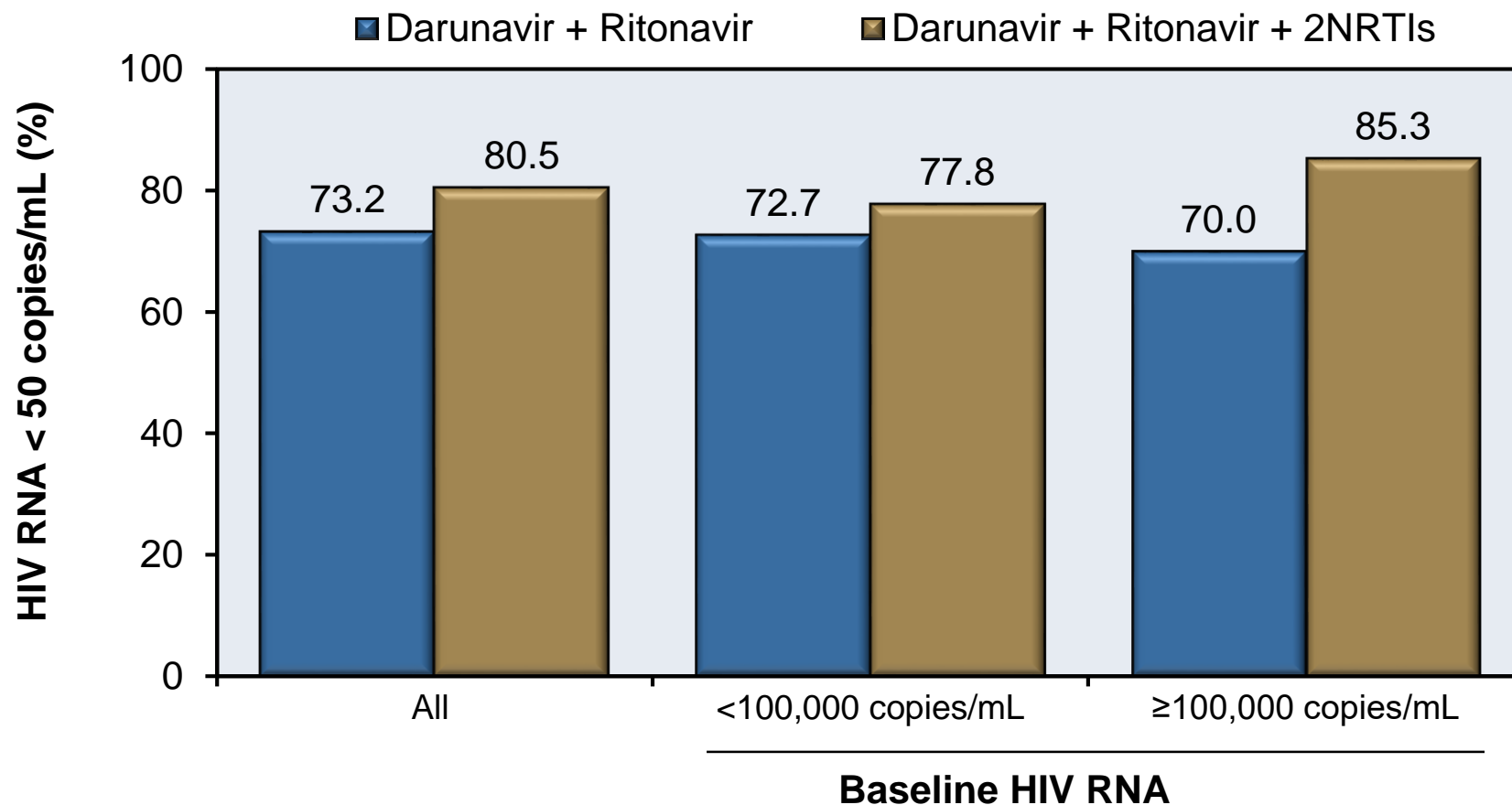
Week 48: HIV RNA <50 copies/mL, by Baseline HIV RNA (Per Protocol Analysis)



Darunavir/r Monotherapy versus Triple Therapy

MONOI-ANRS 136: Result

Week 48: HIV RNA <50 copies/mL, by Baseline HIV RNA (ITT Analysis)



Darunavir/r Monotherapy versus Triple Therapy

MONOI-ANRS 136: Conclusions

Conclusion: “Darunavir/r monotherapy exhibited efficacy rate over 85% with concordant results in the magnitude of difference with darunavir/r triple drug regimen in both intent-to-treat and per protocol analyses, but discordant conclusions with respect to the noninferiority margin. Patients failing on darunavir/r monotherapy had no emergence of new darunavir resistance mutations preserving future treatment options.”

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.

