Darunavir/r versus Lopinavir/r in Treatment-Naïve

ARTEMIS Trial

Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve ARTEMIS: Study Design

Study Design: ARTEMIS

- **Background**: Randomized, open-label phase 3 trial comparing the efficacy and safety of once-daily darunavir/ritonavir with lopinavir/ritonavir in treatment-naïve patients with HIV infection
- **Inclusion Criteria (n = 689)**
  - Age ≥18
  - Antiretroviral-naïve patients
  - HIV RNA ≥5000 copies/mL
  - No AIDS-defining illness
- **Treatment Arms**
  - DRV 800 mg QD + RTV 100 mg QD + TDF-FTC
  - LPV/r 800/200 mg QD (or 400 mg bid) + TDF-FTC

DRV + RTV + TDF-FTC
(n = 343)

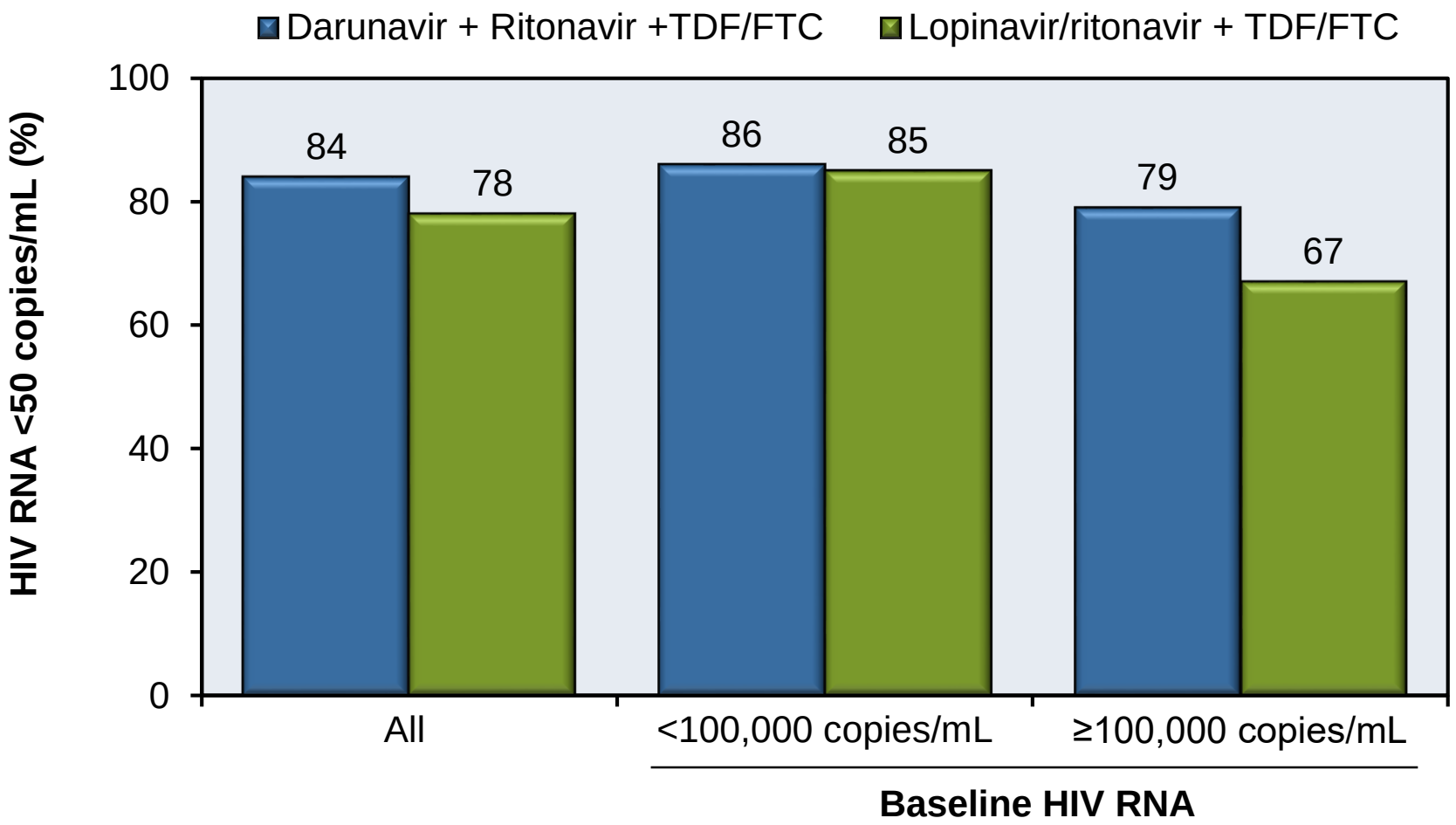
LPV/RTV + TDF-FTC
(n = 346)

ARTEMIS = **A**nti**R**etroviral **T**herapy with TMC114 **E**xa**M**ined **I**n naive **S**ubjects

Source: Ortiz R, et al. AIDS. 2008;22:189-97.

Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve ARTEMIS: Results at 48 Weeks

Week 48: Virologic Response (Intent-to-Treat Analysis)



Source: Ortiz R, et al. AIDS. 2008;22:189-97.

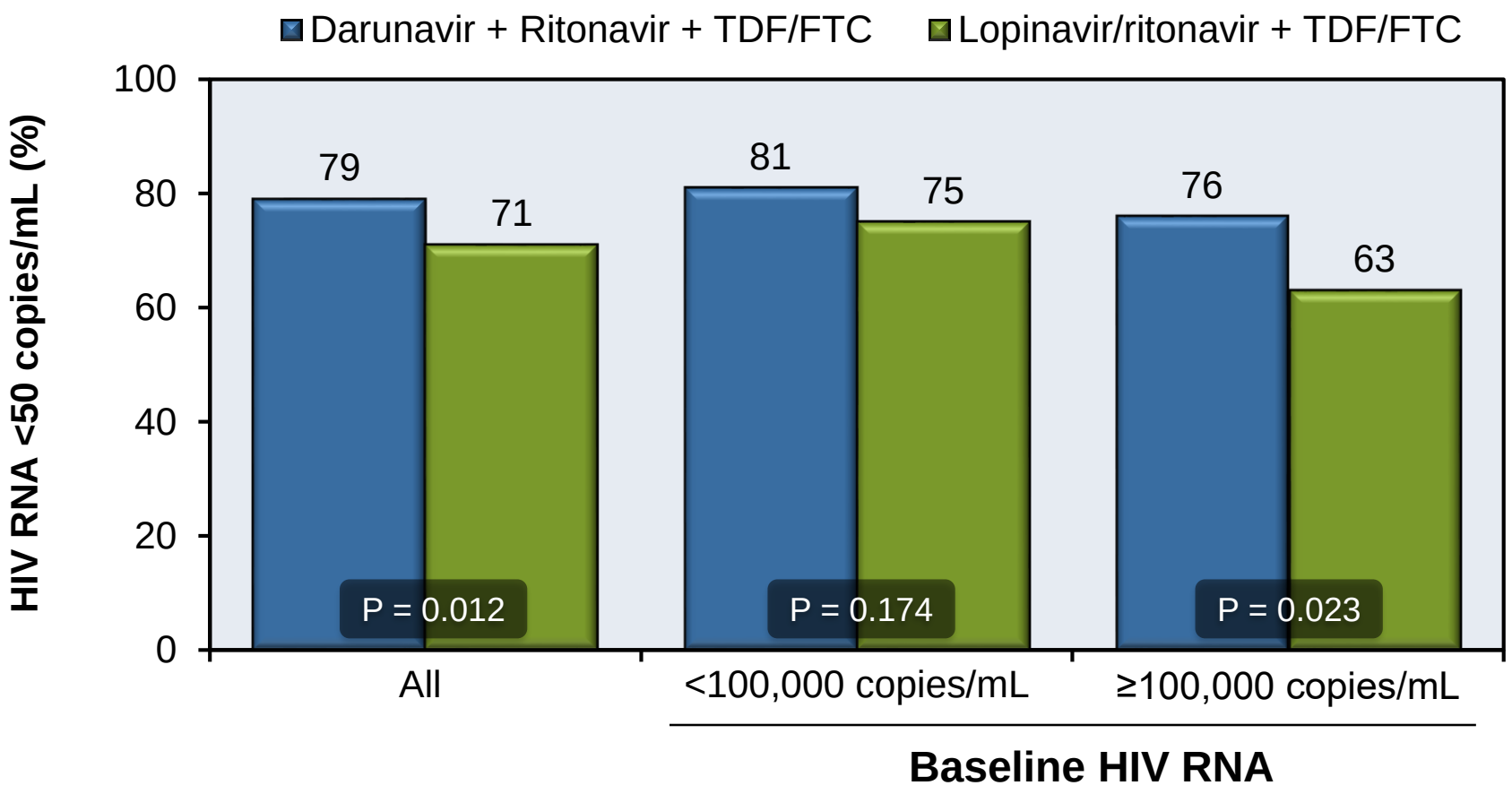
Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve ARTEMIS: Conclusions (48 Week Data)

Conclusion: “DRV/r 800/100 mg qd was non-inferior to LPV/r 800/200 mg at 48 weeks, with a more favorable safety profile. Significantly higher response rates were observed with DRV/r in patients with HIV-1 RNA at least 100 000 copies/ml. DRV/r 800/100 mg offers a new effective and well tolerated once-daily, first-line treatment option for treatment-naive patients.”

Source: Ortiz R, et al. AIDS. 2008;22:189-97.

Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve ARTEMIS: Results at 96 Weeks

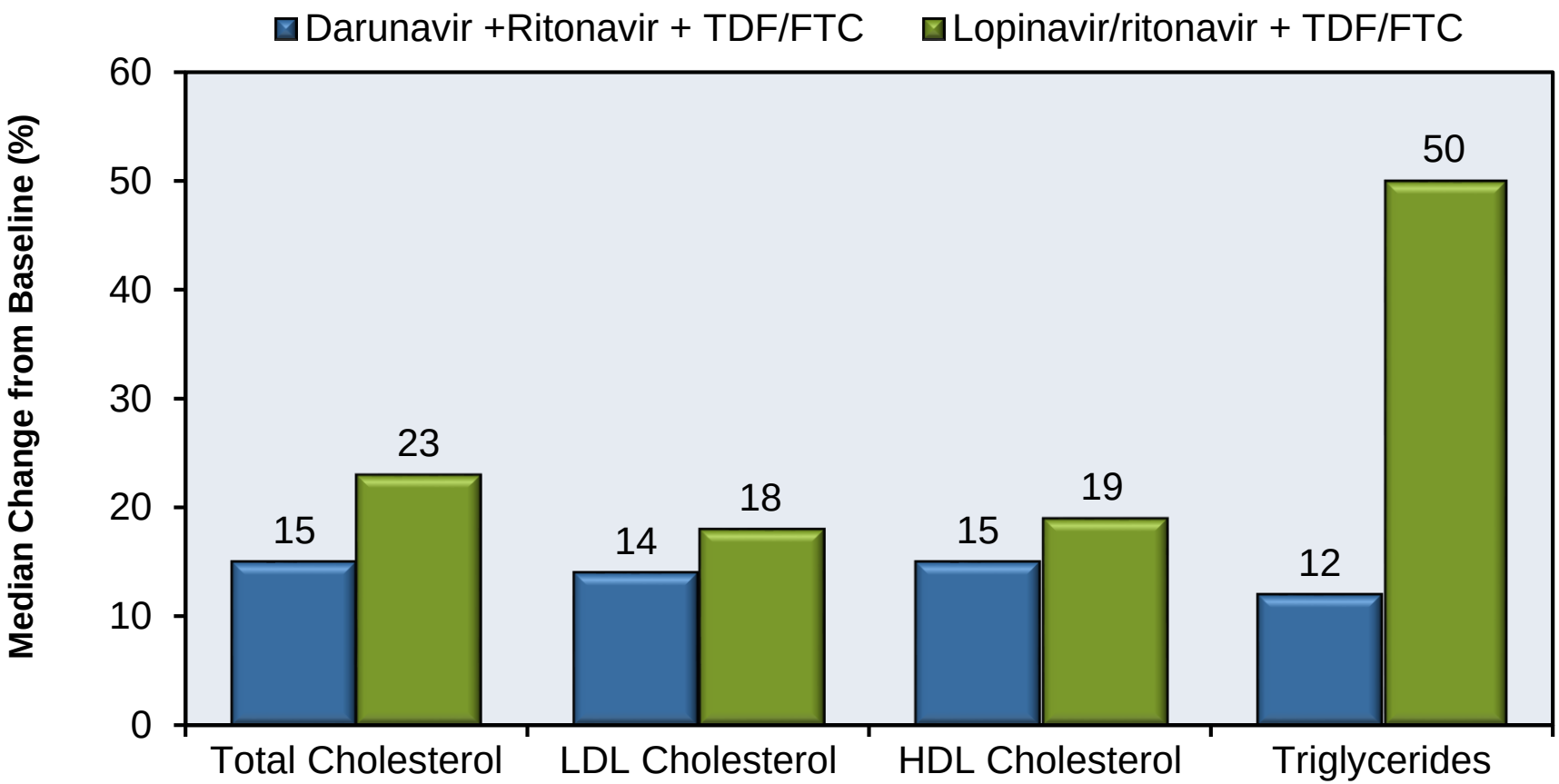
Week 96: Virologic Response (Intent-to-Treat Analysis)



Source: Mills AM, et al. AIDS. 2009;23:1679-88.

Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve ARTEMIS: Results at 96 Weeks

Week 96: Analysis of Lipids



Source: Mills AM, et al. AIDS. 2009;23:1679-88.

Once Daily Darunavir/r versus Lopinavir/r in Treatment-Naïve ARTEMIS: Conclusions (96 Week Data)

Conclusion: “At week 96, once-daily DRV/r was both statistically noninferior and superior in virologic response to LPV/r, with a more favorable gastrointestinal and lipid profile, confirming DRV/r as an effective, well tolerated, and durable option for antiretroviral-naive patients.”

Source: Mills AM, et al. AIDS. 2009;23:1679-88.

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.

National HIV Curriculum

AETC AIDS Education & Training Center Program
National Coordinating Resource Center