Darunavir/r versus Other PIs in Treatment Experienced

POWER 1 and 2

Darunavir/r versus other PIs in Treatment-Experienced
POWER 1 and 2: Study Design

Study Design: POWER 1 and 2

- **Background**: Two randomized, phase 2b trials to compare the efficacy and safety of ritonavir-boosted darunavir with other protease inhibitors in treatment-experienced HIV-infected patients with PI resistance
- **Inclusion Criteria (n = 155)**
  - Age ≥18
  - HIV RNA >1000 copies/mL
  - On PI-containing regimen
  - History of taking >1 NRTI, and ≥1 NNRTI as part of failing regimen
  - At least 1 primary PI mutation at screening
- **Treatment Arms**
  - Darunavir 600 mg BID + Ritonavir 100 mg bid + OBR*
  - Investigator-selected control PI + OBR*

Darunavir BID + RTV BID + OBR
(n = 131)

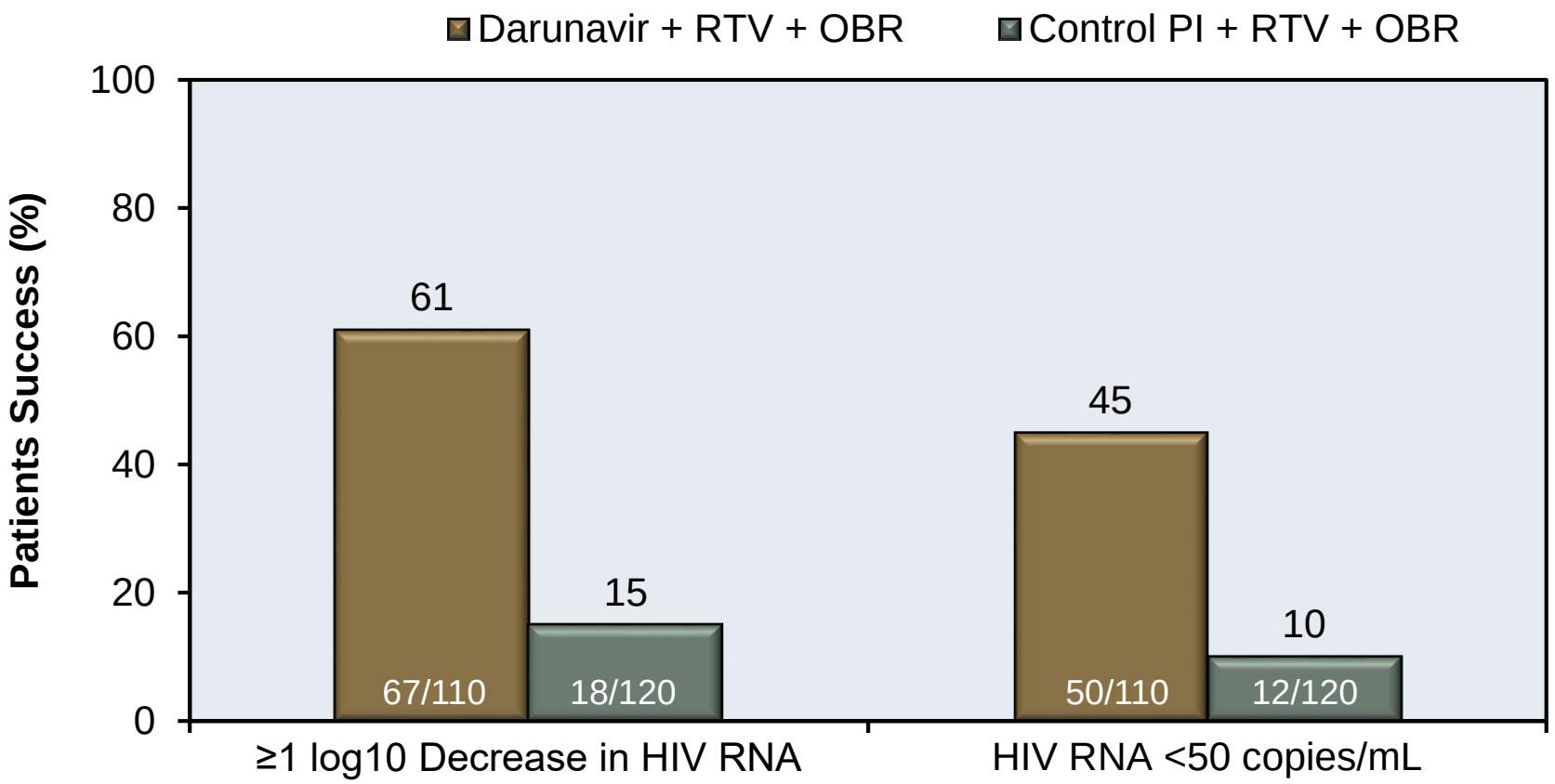
Control PI + RTV + OBR
(n =124)

*OBR = Optimized background regimen: ≥2 NRTIs +/- enfurvirtide

Source: Clotet B, et al. Lancet. 2007;369:1169-78.

Darunavir/r versus other PIs in Treatment-Experienced
POWER 1 and 2: Result

Week 48: Virologic Response



Source: Clotet B, et al. Lancet. 2007;369:1169-78.

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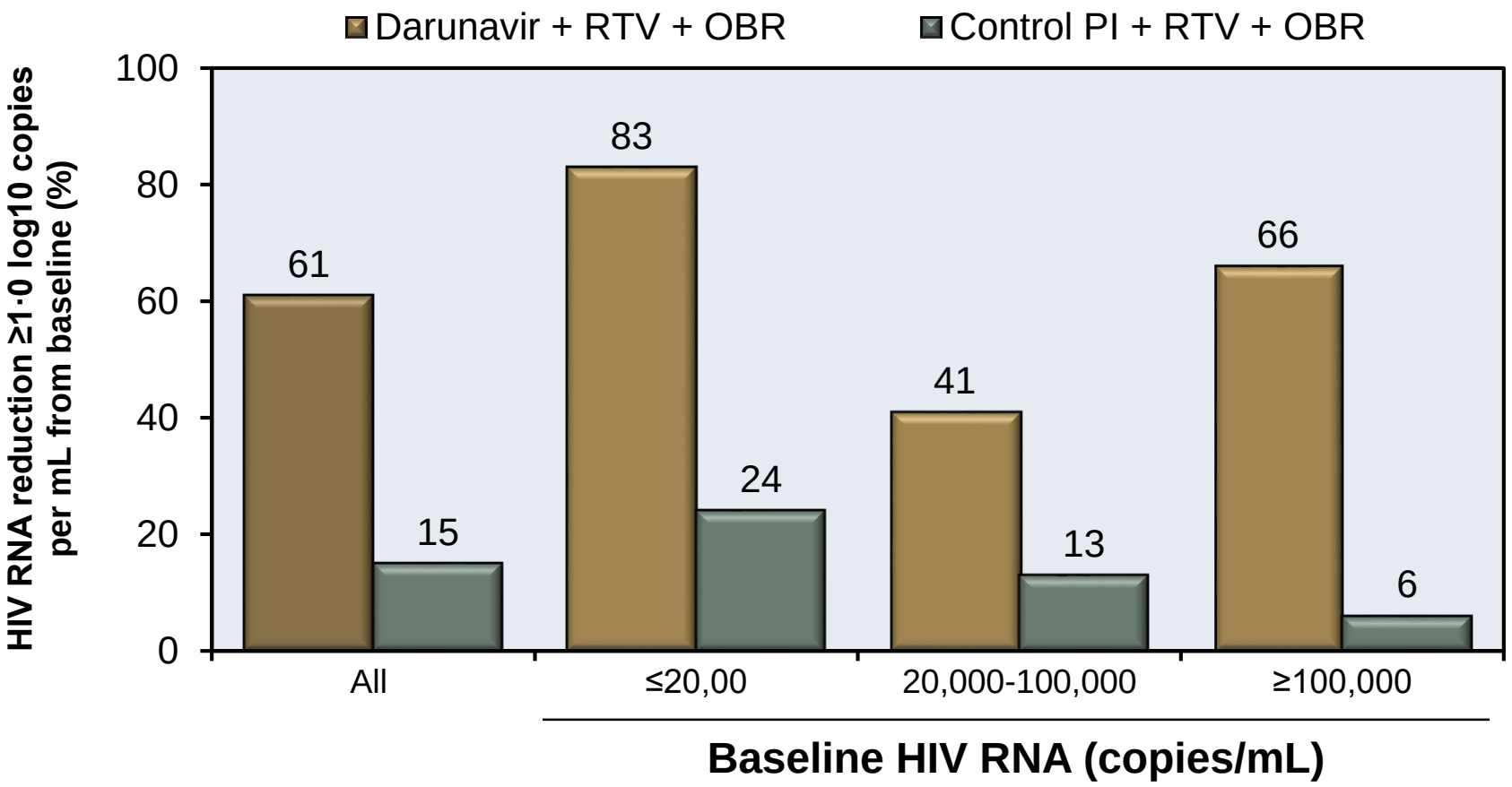
Darunavir/r versus other PIs in Treatment-Experienced
POWER 1 and 2: Result

Week 48: Virologic Response (ITT-TLOVR)



Source: Clotet B, et al. Lancet. 2007;369:1169-78.

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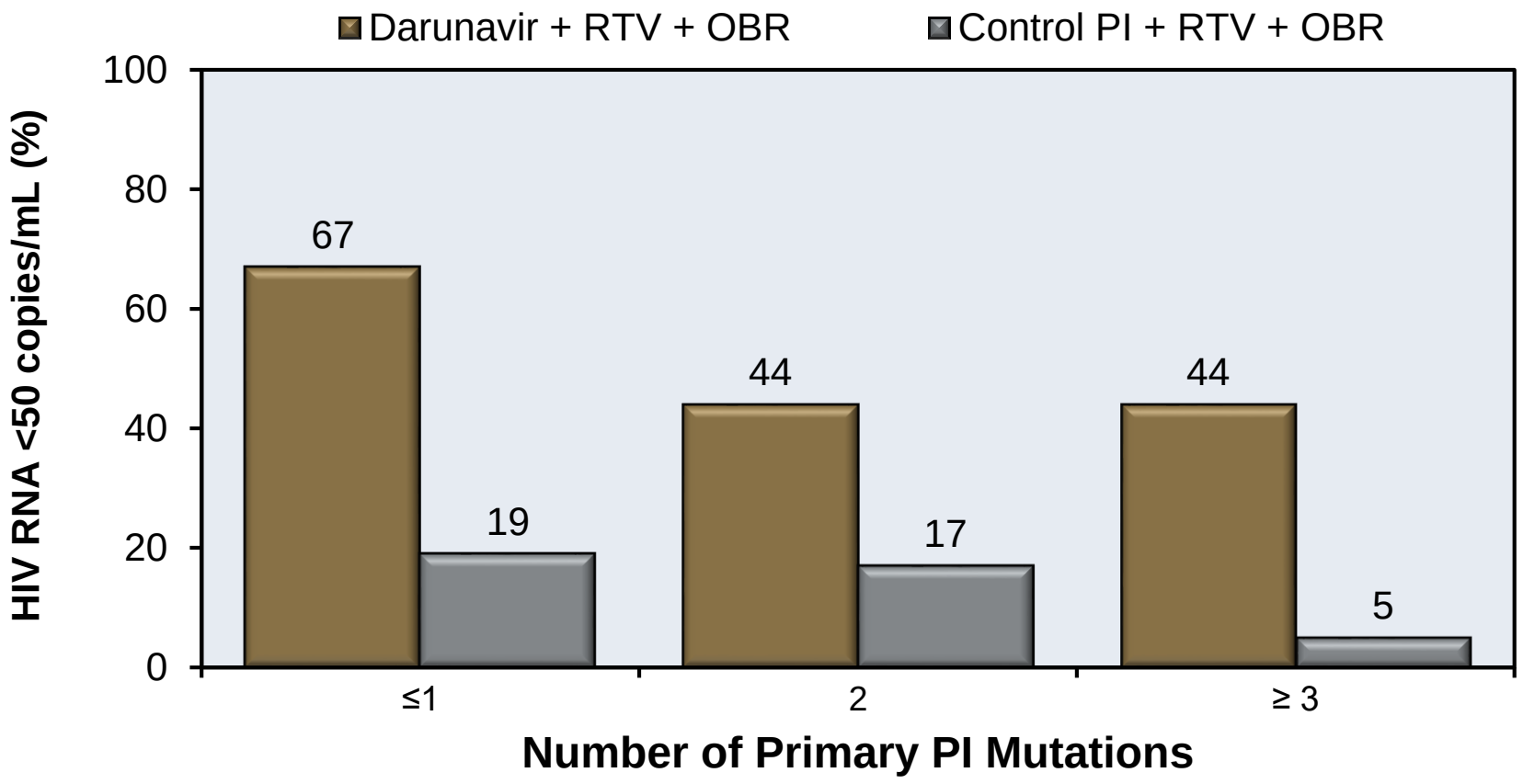
Darunavir/r versus other PIs in Treatment-Experienced
POWER 1 and 2: Result

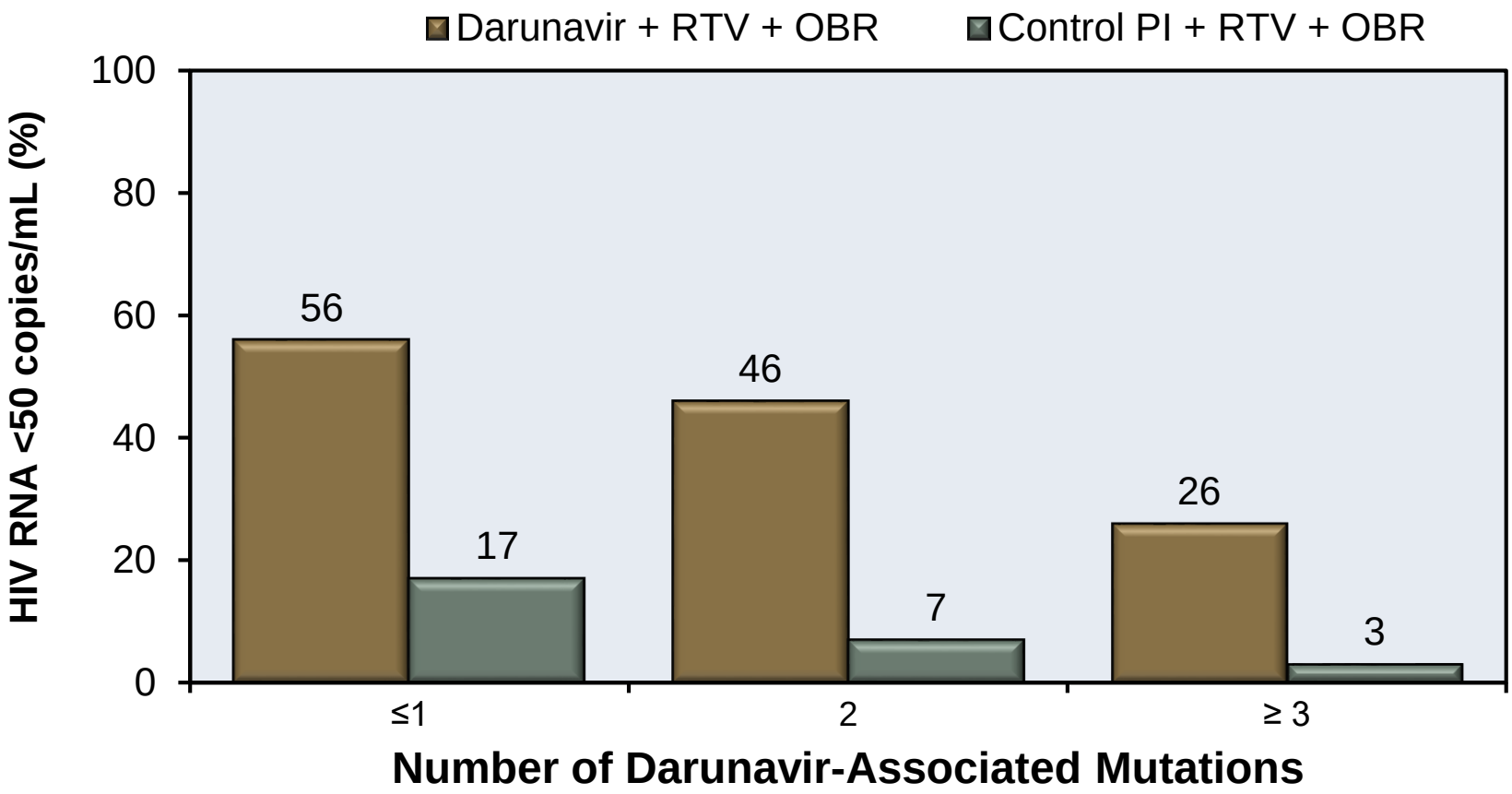
Week 48: Virologic Response, by Primary PI Mutations at Baseline



Source: Clotet B, et al. Lancet. 2007;369:1169-78.

Darunavir/r versus other PIs in Treatment-Experienced
POWER 1 and 2: Result

Week 48: Virologic Response, by DRV-Associated Mutations at Baseline



Source: Clotet B, et al. Lancet. 2007;369:1169-78.

Darunavir/r versus other PIs in Treatment-Experienced POWER 1 and 2: Result

ACTG Grade 3 or 4 Adverse Events (≥ 1% incidence regardless of causality)		
Data given for Number of Patients	**DRV + RTV + OBR** (n = 131)	**Control PI + RTV + OBR** (n = 124)
Abdominal pain	3	0
Neutropenia	2	3
Diarrhea	2	2
Injection site reaction (2° enfuvirtide)	2	1
Acute renal failure	2	1
Hip arthroplasty	2	0
Peripheral neuropathy	2	0
Anemia	2	0
Weight decreased	2	0
Pneumonia	2	0
Fatigue	1	2
Hyperbilirubinemia	0	3
Herpes zoster	0	2

Source: Clotet B, et al. Lancet. 2007;369:1169-78.

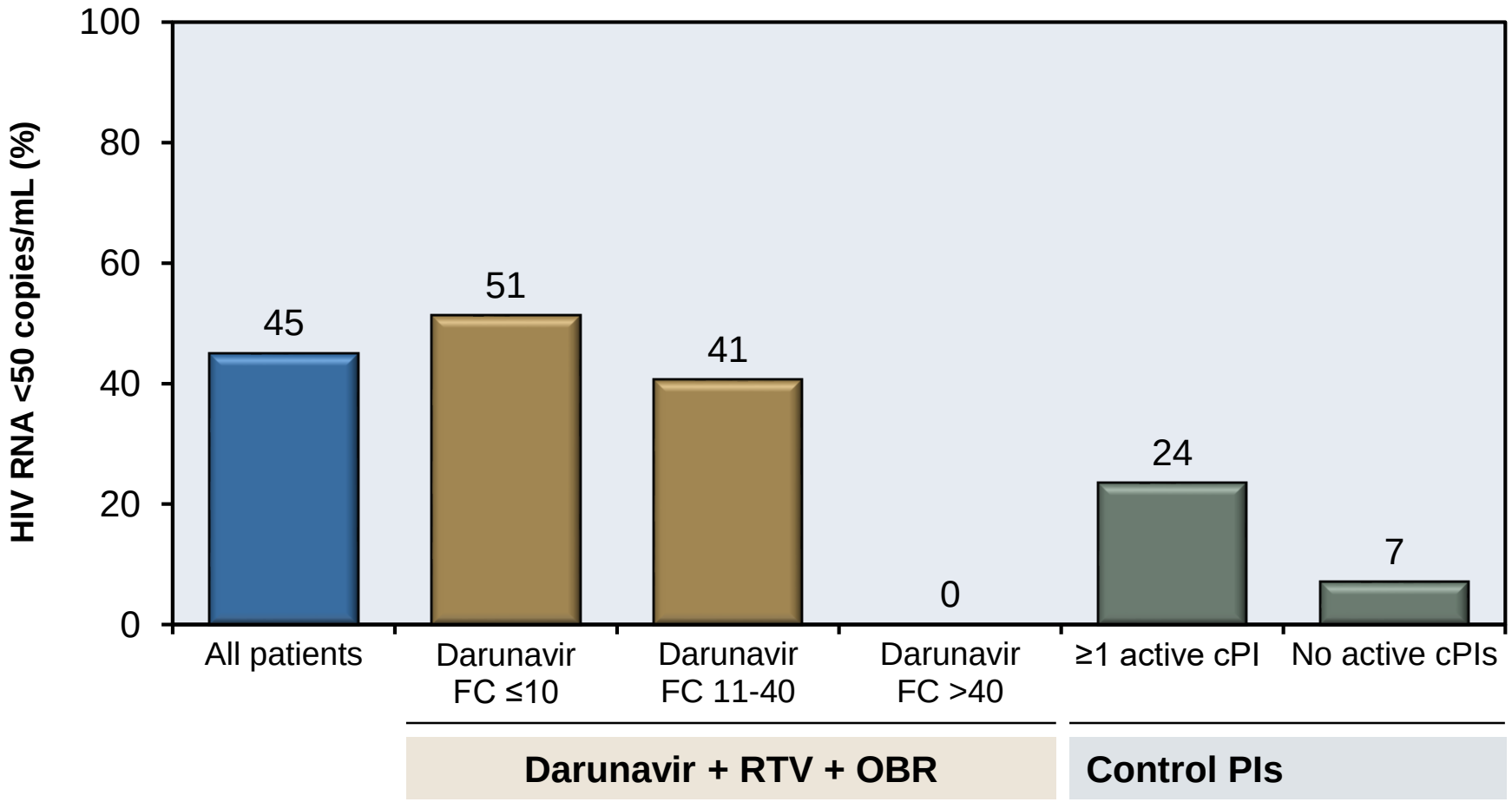
Darunavir/r versus other PIs in Treatment-Experienced
POWER 1 and 2: Conclusions

Interpretation: “Efficacy responses with darunavir-ritonavir 600/100 mg twice daily plus optimised background regimen were greater than those with control PI and were sustained to at least week 48, with favourable safety and tolerability in treatment-experienced patients. This regimen could expand the treatment options available for such patients.”

Source: Clotet B, et al. Lancet. 2007;369:1169-78.

Darunavir/r versus other PIs in Treatment-Experienced
POWER 1 and 2: Result

Week 24: Virologic Response, by Viral Susceptibility at Baseline



Source: Posniak A, et al. AIDS Res Hum Retroviruses. 2008;24:1275-80.

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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