Darunavir/r vs. Tipranavir/r in Treatment Experienced

# POWER 3

# Darunavir/r in Treatment-Experienced
# POWER 3: Study Design

## Study Design: POWER 3

- **Background**: Analysis of phase 2b nonrandomized, open-label evaluating the efficacy and safety of darunavir 600 mg twice daily plus ritonavir 100 mg twice daily, with OBR, in treatment-experienced persons with HIV infection
- **Inclusion Criteria (n=327)**
  - Age ≥18
  - HIV RNA >1000 copies/mL
  - On PI-containing regimen x 3 months,
  - Prior NRTI and NNRTI treatment
  - At least 1 primary PI mutation at screening
  - Darunavir-naïve
- **Treatment Arms**
  - Darunavir 600 mg BID + RTV 100 mg bid + OBR*

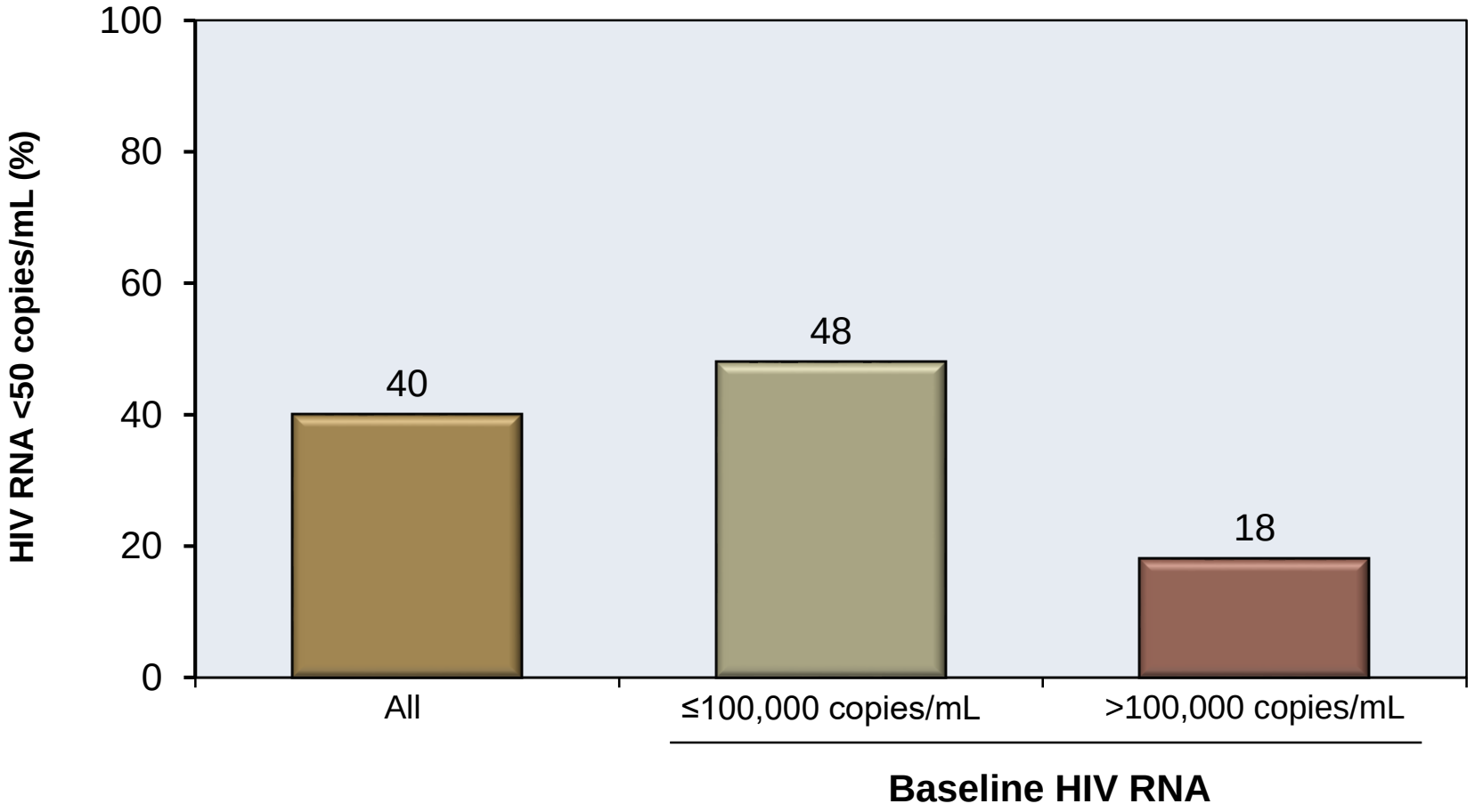
→ **Darunavir BID + RTV BID + OBR** (n = 327)

*OBR = Optimized background regimen: NRTIs +/- enfuvirtide

**Source: Molina JM, et al. J Acquir Immune Defic Syndr. 2007;46:24-31.**

# Darunavir/r in Treatment-Experienced
# POWER 3: Result

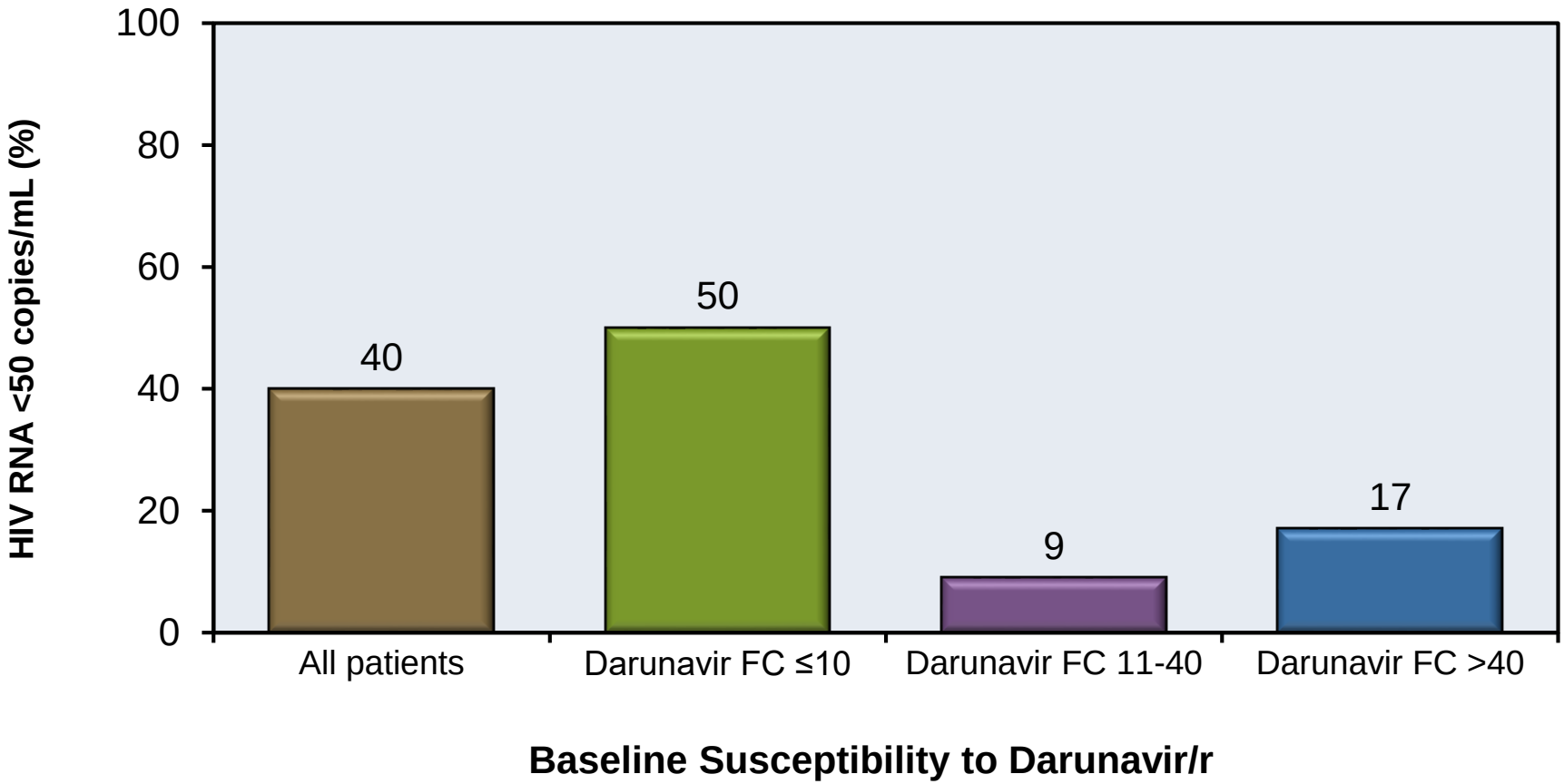
## Week 24: Virologic Response, by Baseline HIV RNA ( ITT-TLOVR)




Source: Molina JM, et al. J Acquir Immune Defic Syndr. 2007;46:24-31.

# Darunavir/r in Treatment-Experienced
# POWER 3: Result

## Week 24: Virologic Response, by Viral Susceptibility at Baseline




Source: Molina JM, et al. J Acquir Immune Defic Syndr. 2007;46:24-31.

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

| Safety Parameters | |
|---|---|
| **Side Effect, n (%)** | **DRV + RTV + OBR** (n = 327) |
| Most frequently reported (≥10%) Adverse Effects, regardless of severity or causality | |
| Diarrhea | 45 (14) |
| Nasopharyngitis | 31 (11) |
| Nausea | 33 (10) |
| Treatment-emergent ACTG grade 3 or 4 adverse events reported with incidence of ≥2%, regardless of causality | |
| Any grade 3 or 4 adverse event | 83 (25) |
| Diarrhea | 5 (2) |
| Neutropenia | 5 (2) |

**Source: Molina JM, et al. J Acquir Immune Defic Syndr. 2007;46:24-31.**

# Darunavir/r in Treatment-Experienced
# POWER 3: Conclusions

**Conclusions**: “These results corroborate POWER 1 and POWER 2. In this larger set of treatment-experienced patients, darunavir/r at a dose of 600/100 mg twice daily provided substantial virologic and immunologic responses and was generally safe and well tolerated.”

**Source: Molina JM, et al. J Acquir Immune Defic Syndr. 2007;46:24-31.**

# 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

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