

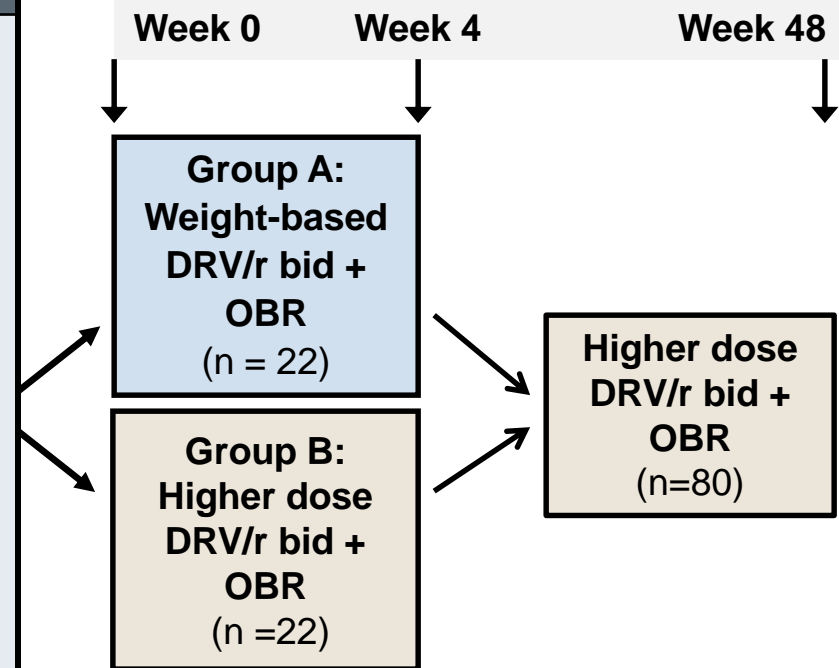
Darunavir/r in Treatment-Experienced Children and Adolescents  
**DELPHI Trial**

# Darunavir/r in Treatment-Experienced Children and Adolescents

## DELPHI: Study Design

### Study Design: DELPHI

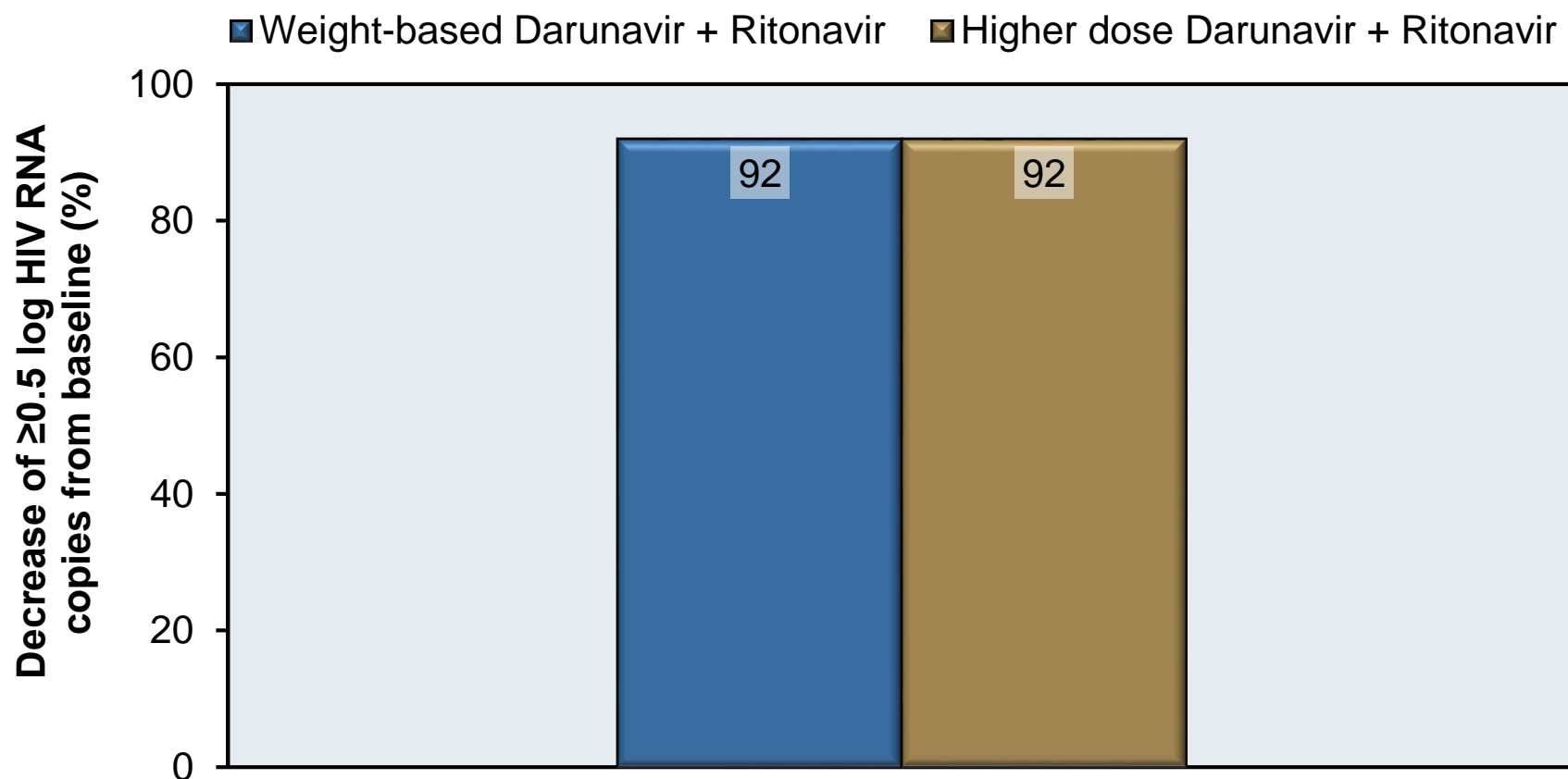
- **Background:** Open-label, phase 2 trial evaluating the pharmacokinetics, safety, and efficacy of darunavir + ritonavir + OBR in treatment-experienced children/adolescents with HIV infection
- **Inclusion Criteria (Part I: n=44, Part II: n=80)**
  - Age 6 to 17, treatment-experienced
  - Body weight  $\geq 20$  kg
  - HIV RNA  $> 1000$  copies/mL
  - Stable CD4%
- **Treatment Arms**
  - Group A (weight-based): DRV 9-15 mg/kg + RTV 1.5-2.5 mg/kg bid + OBR\*
  - Group B (higher dose): DRV 11-19 mg/kg + RTV 1.5-2.5 mg/kg bid + OBR\*



**DELPHI** = **D**arunavir **E**va**L**uation in **P**ediatric, **H**IV-**I**nfected, treatment-experienced patients  
\*Optimized background regimen =  $\geq 2$  active antiretroviral agents (NRTIs, EFV, NVP, or ENF)

# Darunavir/r in Treatment-Experienced Children and Adolescents DELPHI: Result

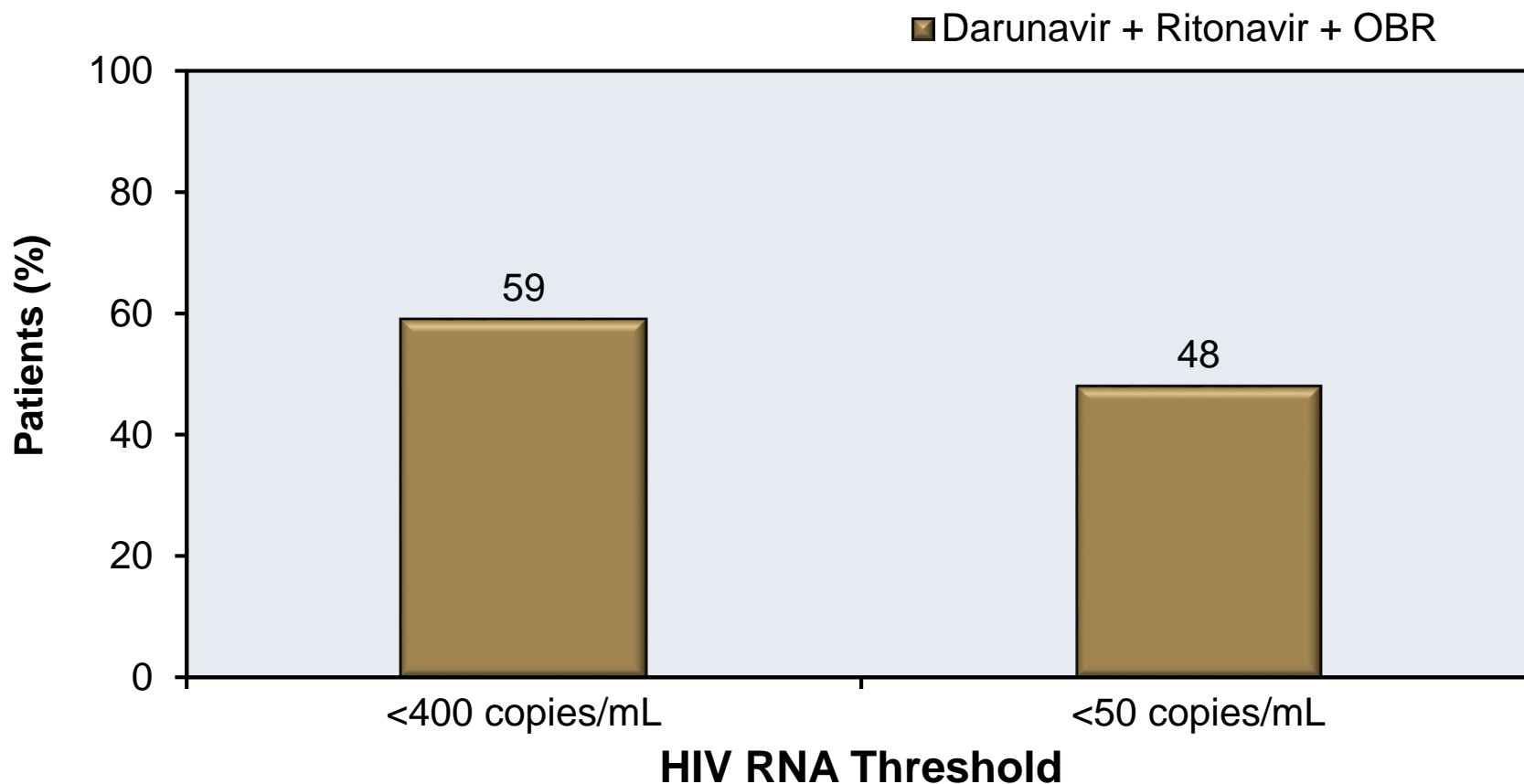
Week 4: Virologic Response (ITT Analysis)



Source: Blanche S, et al. AIDS. 2009;23:2005-13.

# Darunavir/r in Treatment-Experienced Children and Adolescents DELPHI: Result

Week 48: Virologic Response (TLOVR)



# Darunavir/r in Treatment-Experienced Children and Adolescents

## DELPHI: Conclusions

**Conclusion:** “In treatment-experienced children and adolescents, DRV/r showed comparable exposure to adults with appropriate dose selection, favorable safety and tolerability, improved body weight and significant virologic response. DRV/r is a valuable therapeutic option for this population.”

# 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.*

