Darunavir/r in Treatment-Naïve Adolescents

DIONE Trial

Darunavir/r in Treatment-Naïve Adolescents
DIONE: Study Design

Study Design: DIONE Study

- **Background**: Open-label, single-arm, phase 2 trial to evaluate the pharmacokinetics, safety, and efficacy of once-daily darunavir + ritonavir + 2NRTIs treatment-naïve adolescents with HIV Infection
- **Inclusion Criteria (n = 12)**
  - Age ≥12 to < 18 years old
  - ≥40 kg
  - Antiretroviral-naïve
  - HIV RNA ≥1000 copies/mL
- **Treatment Arm**
  - Darunavir 800 mg QD + RTV 100 mg QD + *2NRTIs

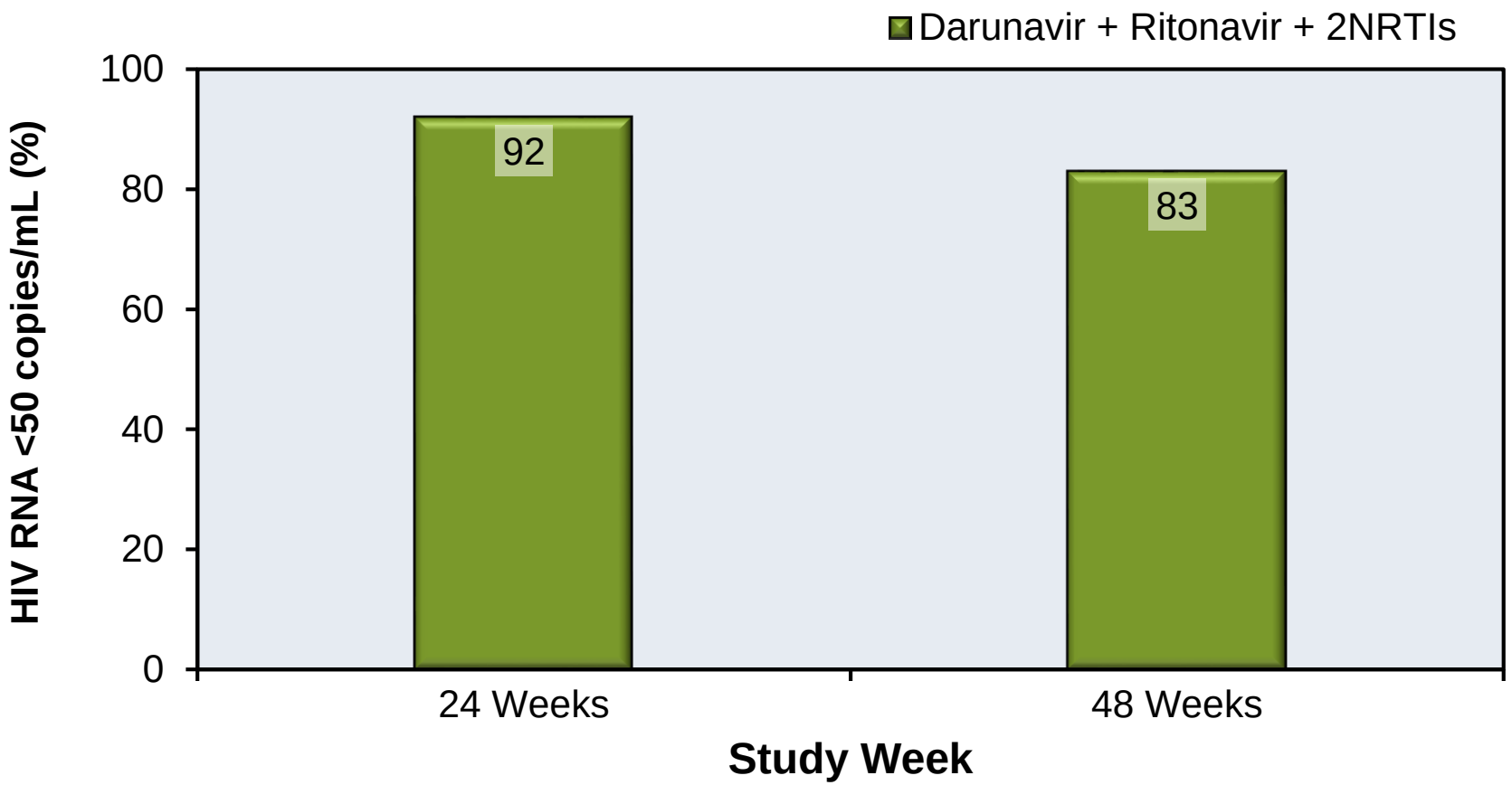
→ **Darunavir 800 mg QD + Ritonavir 100 mg QD + 2 NRTIs** (n = 12)

*2NRTIs = Zidovudine-lamivudine or Abacavir-lamivudine

Source: Flynn P, et al. Pediatr Infect Dis J. 2014;33:940-5.

Darunavir/r in Treatment-Naïve Adolescents
DIONE: Result

Week 48: Virologic Response (ITT-TLOVR)



Source: Flynn P, et al. Pediatr Infect Dis J. 2014;33:940-5.

Darunavir/r in Treatment-Naïve Adolescents
DIONE: Result

Week 48: Overview of Adverse Events and Laboratory Abnormalities		
	Any Causality (n=12)	**Possibly related to Darunavir + Ritonavir (n=12)**
≥ 1 adverse event	11 (92%)	2 (17%)
≥ 1 grade 3 or 4 adverse event	3 (25%)	0
≥ 1 serious adverse event	4 (33%)	1 (8%)
≥ 1 adverse event leading to discontinuation	0	0
Grade 2-4 laboratory abnormalities		
Total cholesterol (≥ 200mg/dL)	4 (33%)	
LDL (≥130 mg/dL)	3 (25%)	
Triglycerides (≥500mg/dL)	0 (0%)	
High serum glucose (≥125 mg/dL)	1 (8%)	

Source: Flynn P, et al. Pediatr Infect Dis J. 2014;33:940-5.

Darunavir/r in Treatment-Naïve Adolescents
DIONE: Conclusions

Conclusions: “Over 48 weeks, once-daily darunavir/ritonavir 800/100 mg plus NRTIs was effective and well-tolerated for treatment of HIV-1-infected, antiretroviral-naïve adolescents (≥12 to <18 years). These findings support use of once-daily darunavir/ritonavir 800/100 mg in this population.”

Source: Flynn P, et al. Pediatr Infect Dis J. 2014;33:940-5.

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