Darunavir /r in Treatment-Experienced Pediatric Patients

ARIEL Trial

Darunavir/r in Treatment-Experienced Pediatric Patients
ARIEL: Study Design

Study Design: ARIEL

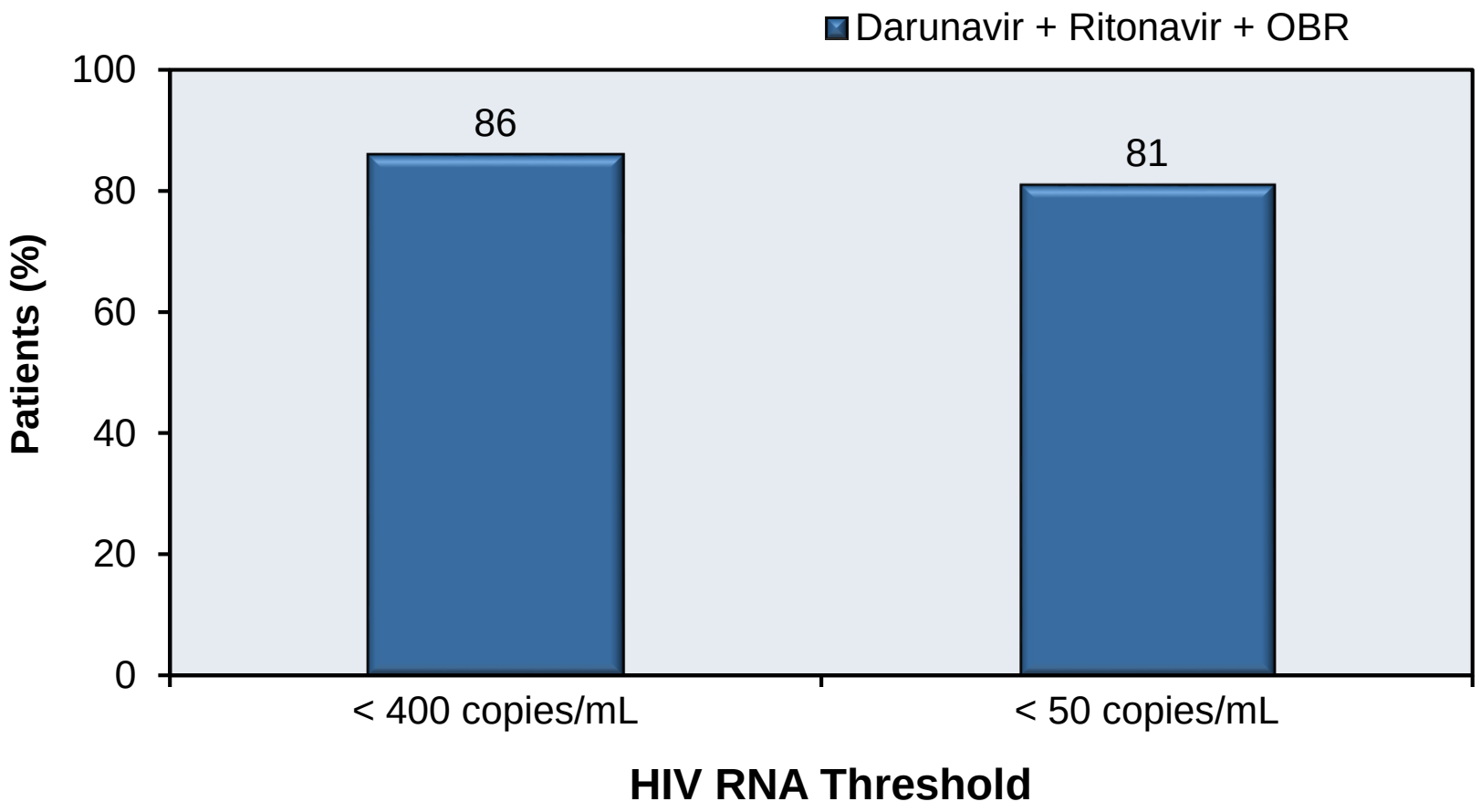
- **Background**: Open-label, single-arm, phase 2 trial to evaluate the pharmacokinetics, safety, tolerability, and efficacy of twice-daily of darunavir + ritonavir in treatment-experienced children with HIV infection
- **Inclusion Criteria (n = 21)**
  - Age 3 to <6 years old
  - 10 to <20 kg at screening
  - On stable ART regimen ≥12 weeks
  - HIV RNA >1000 copies/mL
- **Treatment Arm**
  - Darunavir/ritonavir 20/3 mg/kg bid x 2 weeks, (then adjusted to 25/3 mg/kg twice-daily for patients <15 kg, and 375/50 mg twice-daily for patients 15 to <20 kg) + investigator-selected optimized background regimen (OBR)

→ **Darunavir + Ritonavir + OBR**
(n = 21)

Source: Violari A, et al. Pediatr Infect Dis J. 2015;34:e132-7.

Darunavir/r in Treatment-Experienced Pediatric Patients
ARIEL: Result

Week 48: Virologic Response (ITT-TLOVR)



Source: Violari A, et al. Pediatr Infect Dis J. 2015;34:e132-7.

Darunavir/r in Treatment-Experienced Pediatric Patients
ARIEL: Result

Overview of Adverse Events		
	Before Dose Adjustment (n = 21)	**After Dose Adjustment** (n = 20)
≥ 1 adverse event	14 (66.7%)	17 (85%)
≥ 1 grade 3 or 4 adverse event	1 (4.8%)	1 (5%)
≥ 1 serious adverse event	1 (4.8%)	1 (5%)
≥ 1 adverse event leading to discontinuation	1 (4.8%)	0
Adverse events (excluding laboratory AEs) in ≥ 10% of patients overall		
Gastrointestinal disorders	7 (33%)	6 (30%)
Pyrexia	2 (9.5%)	1 (5%)
Infections and infestations	7 (33%)	15 (75%)
Injury, poisonings, and procedural complications	1 (4.8%)	2 (10%)
Investigations	1 (4.8%)	3 (15%)
Respiratory, thoracic, and mediastinal disorders	5 (23.8%)	4 (20%)
Skin and subcutaneous tissue disorders	2 (9.5%)	4 (20%)

Source: Violari A, et al. Pediatr Infect Dis J. 2015;34:e132-7.

Darunavir/r in Treatment-Experienced Pediatric Patients
ARIEL: Conclusions

Conclusions: “No new safety concerns were observed over a 48 week period. These results led to lowering the age to 3 years at which darunavir/ritonavir is indicated for use in treatment-experienced pediatric patients. This study also established doses of darunavir to use in treatment-experienced, HIV-1-infected patients aged 3 to <6 years. A high virologic response was observed with this dose. No development of resistance was observed in patients who experienced virologic failure.”

Source: Violari A, et al. Pediatr Infect Dis J. 2015;34:e132-7.

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