Darunavir/r in Treatment-Experienced Children and Adolescents

DELPHI Trial
**Delphi: Study Design**

**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 ≥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** = **Darunavir Evaluation in Pediatric, HIV-Infected, treatment-experienced patients**

*Optimized background regimen = ≥2 active antiretroviral agents (NRTIs, EFV, NVP, or ENF)

Week 4: Virologic Response (ITT Analysis)

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

Week 48: Virologic Response (TLOVR)

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.”

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