

LPV/r +/- SQV in Treatment-Experienced Children
PACTG 1038

LPV-RTV +/- SQV in Treatment-Experienced Children

PACTG 1038: Study Design

Study Design: PACTG 1038

- **Background:** Phase I/II, open-label trial to assess the safety and tolerability of high-dose lopinavir-ritonavir (LPV-RTV) with or without saquinavir (SQV) in protease inhibitor-experienced children with HIV infection
- **Inclusion Criteria (n = 26)**
 - Children aged 2 to 18 years old
 - On PI therapy for ≥ 6 months
 - Failing current regimen: HIV RNA > 5000 copies/mL
 - Phenotypic resistance to LPV ≥ 5 times wild-type
 - CD4 count ≥ 50 cells/mm³
- **Treatment Arms**
 - LPV-RTV 400-100 mg/m² + ≥ 2 NRTIs
 - SQV 750 mg/m² BID added at week 4 if IQ < 15
 - LPV-RTV 480-120 mg/m² BID + NNRTI + ≥ 2 NRTIs
 - SQV 750 mg/m² BID added at week 4 if IQ < 15

Step 1

Step 2: Wk4

LPV-RTV BID +
 ≥ 2 NRTIs
(n=21)

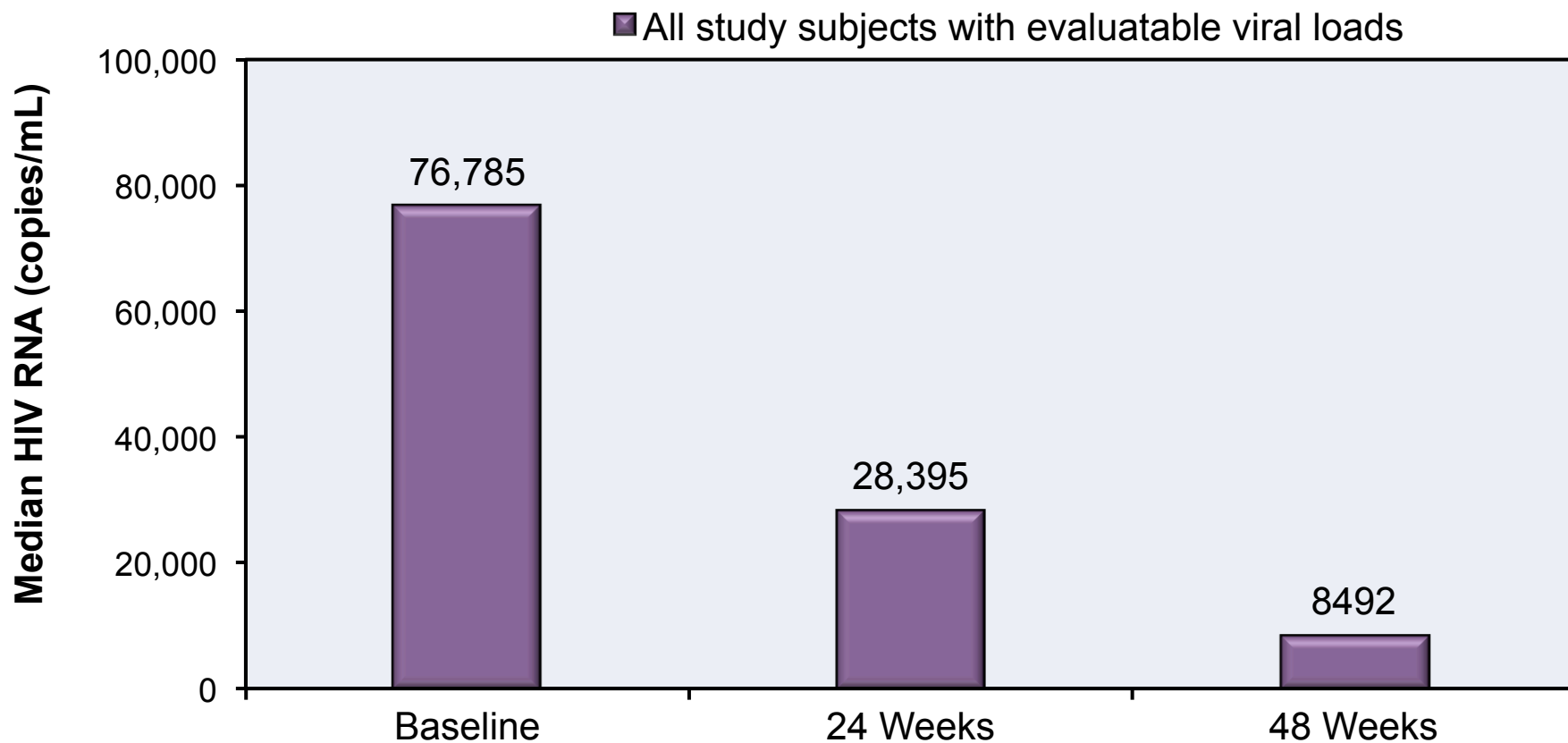
If IQ < 15 , add
SQV BID

LPV-RTV BID +
NNRTI +
 ≥ 2 NRTIs
(n=5)

If IQ < 15 , add
SQV BID

LPV-RTV +/- SQV in Treatment-Experienced Children PACTG 1038: Results

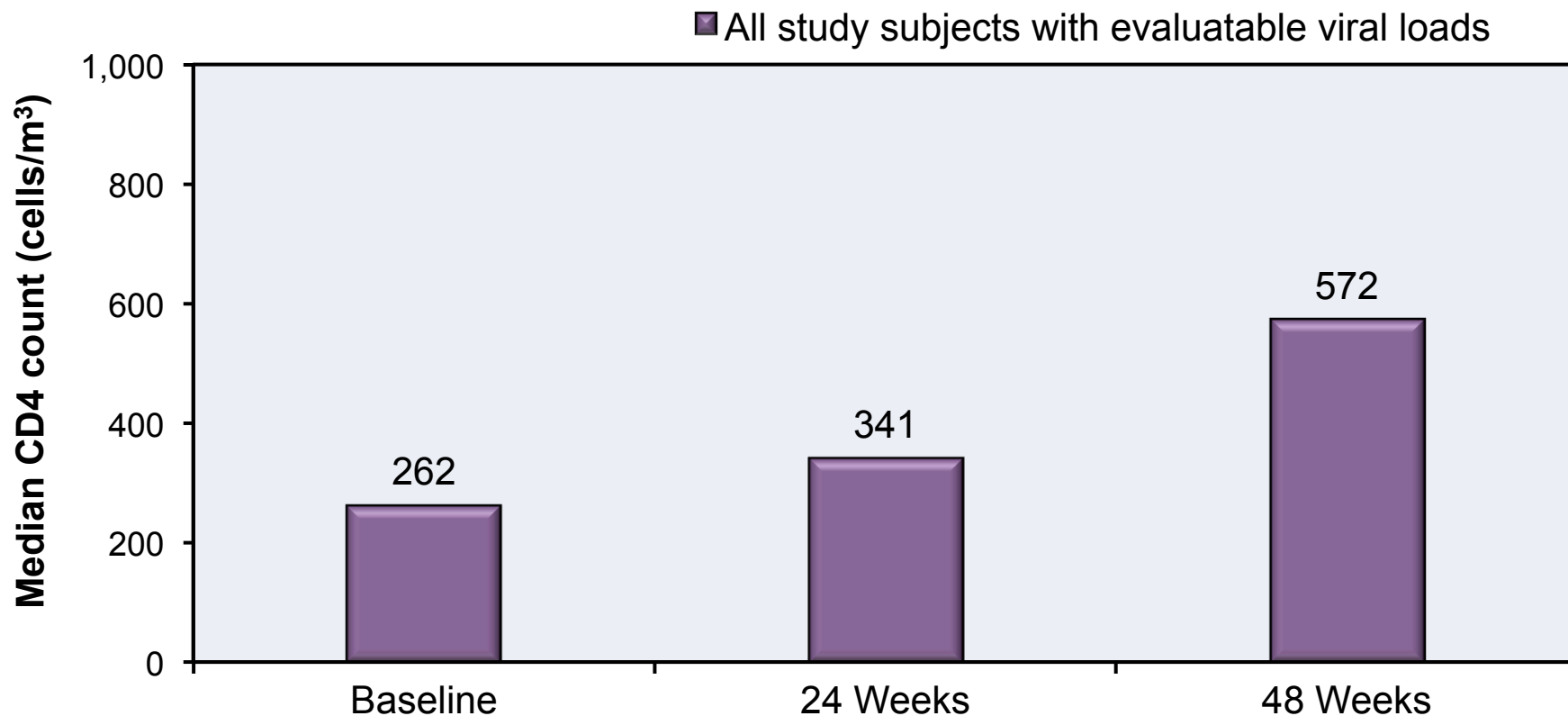
Week 48: Virologic Response



Source: Robbins BL, et al. *Antimicrob Agents Chemother.* 2008;52:3276-83.

LPV-RTV +/- SQV in Treatment-Experienced Children PACTG 1038: Results

Week 48: Immunologic Response



Source: Robbins BL, et al. *Antimicrob Agents Chemother.* 2008;52:3276-83.

LPV/r +/- SQV in Treatment-Experienced Children PACTG 1038: Conclusions

Conclusion: “In antiretroviral-experienced children and adolescents with HIV, high doses of LPV/r with or without SQV offer safe options for salvage therapy, but the modest virologic response and the challenge of adherence to a regimen with a high pill burden may limit the usefulness of this approach.”

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