

Enfuvirtide + Darunavir + RTV in Treatment Experienced
BLQ Study

Enfuvirtide + Darunavir + RTV + OBR in Treatment Experienced BLQ: Study Design

Study Design: BLQ

- **Background:** Prospective, open-label, single-arm phase 4 trial evaluating the efficacy and safety of enfuvirtide in combination with darunavir + ritonavir in triple-antiretroviral-class-experienced adults failing their current regimen
- **Inclusion Criteria (n = 142)**
 - Triple-antiretroviral-class-experienced
 - HIV RNA >2000 copies/mL on current regimen
 - No active untreated opportunistic infection, no grade 4 clinical or laboratory abnormality
- **Treatment Arm**
 - ENF 90 mg SC BID + DRV 600 mg BID + RTV 100 mg BID + investigator-determined optimized background regimen (OBR)

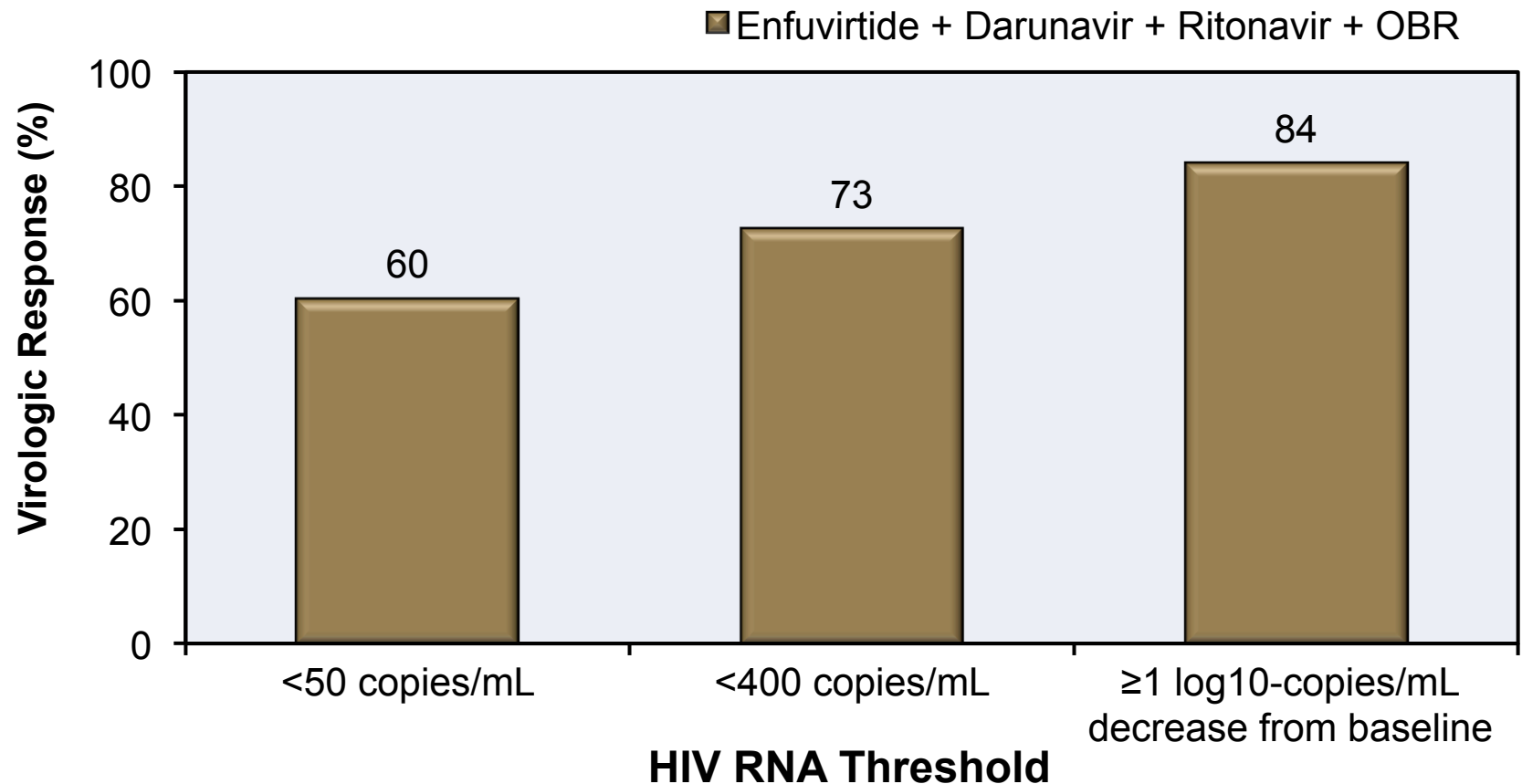
**Enfuvirtide + Darunavir +
Ritonavir + OBR**

(n = 131)

BLQ = **B**elow the **L**evel of **Q**uantification

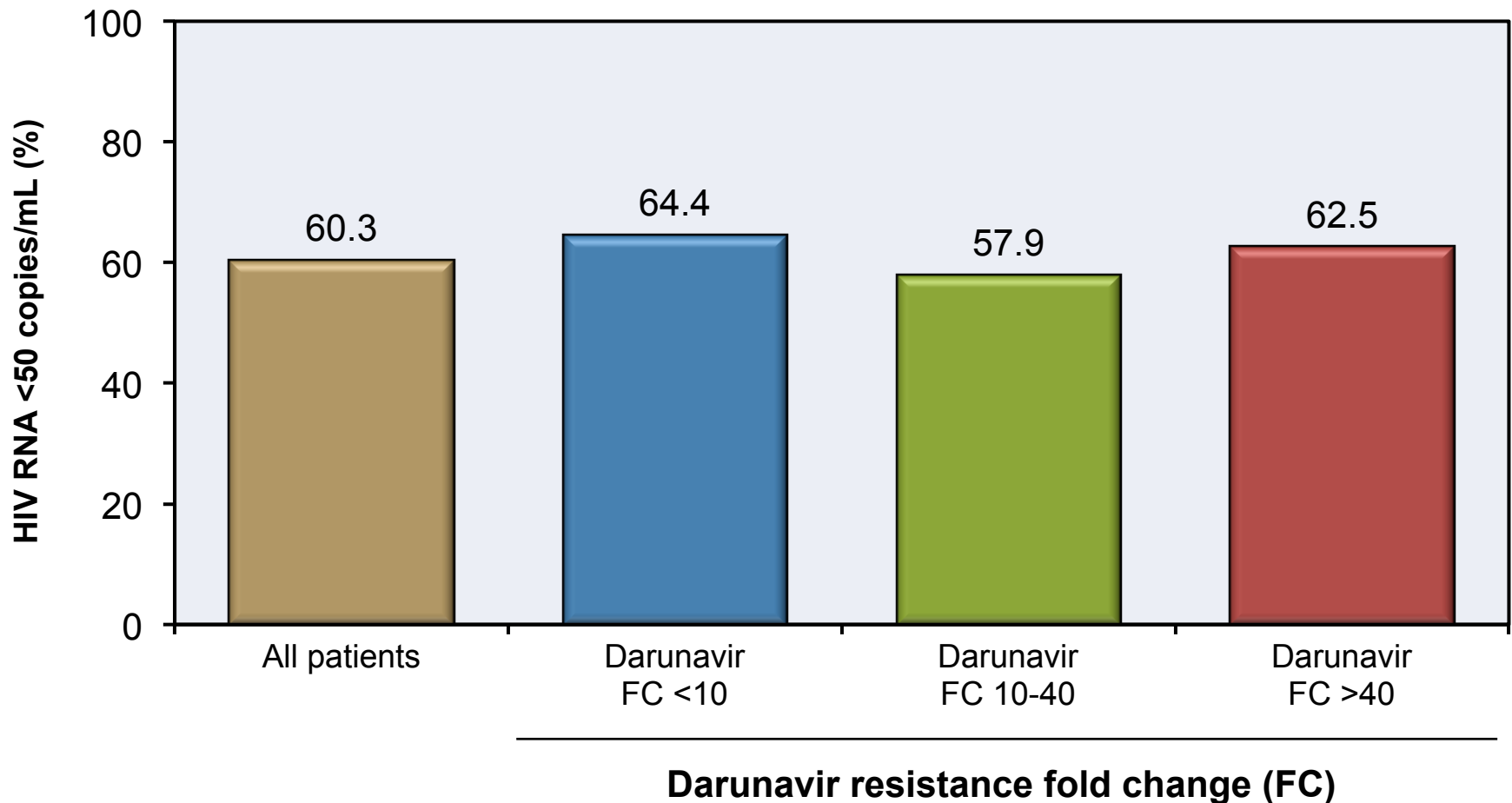
Enfuvirtide + Darunavir + RTV + OBR in Treatment Experienced BLQ Study: Results

Week 24: Virologic Response



Enfuvirtide + Darunavir + RTV + OBR in Treatment Experienced BLQ Study: Results

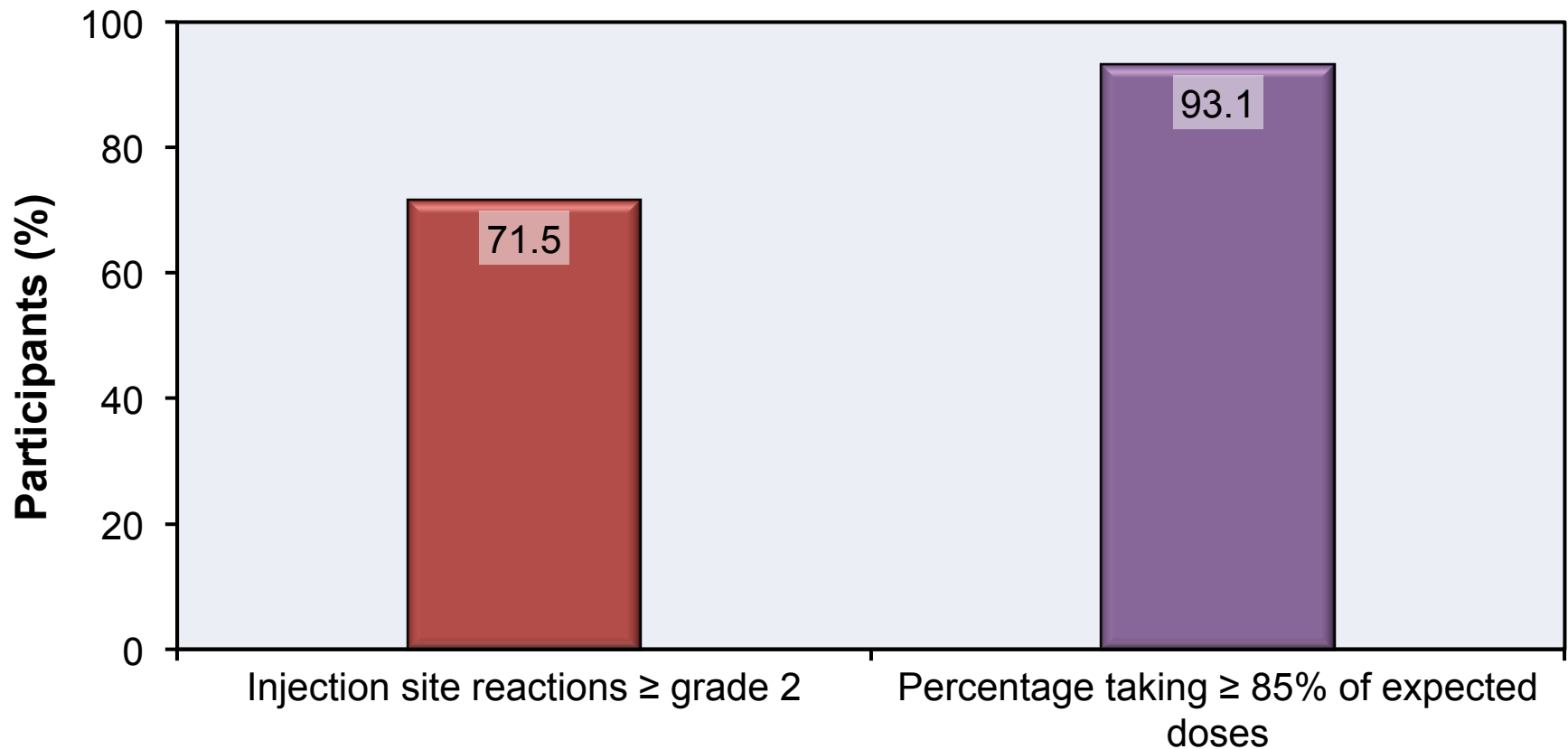
Week 24: Virologic Response, by Darunavir Susceptibility at Baseline



Source: DeJesus E et al. Antimicrob Agents Chemother. 2008;52:4315-9.

Enfuvirtide + Darunavir + RTV + OBR in Treatment Experienced BLQ Study: Results

Injection Site Reactions and Adherence



Enfuvirtide + Darunavir/r in Treatment Experienced BLQ Study: Conclusions

Conclusions: “Although these findings are limited by the relatively small numbers of participants with darunavir susceptibility changes of $>$ or $=10$ -fold, they suggest that combining enfuvirtide and darunavir-ritonavir with an optimized background regimen in triple-class experienced participants naïve to these agents can result in positive virological and immunological responses regardless of most baseline parameters.”

Acknowledgment

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