Efficacy evaluations
The primary endpoint was virologic response (HIV-1 RNA <40 copies/mL) at Week 48.

Methods
Study design and treatment
An open-label, single-arm, Phase III study conducted at 65 sites across the US, Puerto Rico, and Canada.

Study population and baseline characteristics
A total of 429 patients were enrolled in GRACE and received at least one dose of study drug (287 women; 142 men; Figure 2).

Patient population and statistical analysis
To meet the recruitment goal of 420 patients (approximately 70% female, 150 patients expected to discontinue in either group)

Results
Patient population and baseline characteristics
A total of 429 patients were enrolled in GRACE and received at least one dose of study drug (287 women; 142 men).

Safety
Adverse events (AEs), serious AEs and study discontinuations due to AEs were monitored descriptively, including sex, baseline VL and baseline CD4+ count as factors

Conclusions
The GRACE study successfully enrolled a high proportion of women and to date, the largest study in North America to assess sex-based differences in the efficacy and safety of a darunavir-based regimen

References
6. MOPEB042
7. CARDENE
8. SUMMIT

Acknowledgements
The authors also wish to thank the patients and their families, and the principal investigator for their participation in the trial. The authors would also like to thank their clinical research associates for their support with study procedures.

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Presented at the 5th International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention, Cape Town, South Africa, July 19-22, 2009

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