# Darunavir + RTV versus Lopinavir-RTV in Treatment Experienced TITAN Trial



# Darunavir/r versus Lopinavir/r in Treatment-Experienced TITAN: Study Design

#### **Study Design: TITAN**

- Background: Randomized, controlled, open-label, phase 3 trial to compare the efficacy and safety of ritonavir-boosted darunavir versus lopinavirritonavir, both with OBR\*, in treatment-experienced, lopinavir-naïve patients with HIV infection
- Inclusion Criteria (n=595)
  - Adults ≥18 years
  - HIV RNA ≥500 copies/mL
  - Treatment-experienced, lopinavir naïve
- Treatment Arms
  - Darunavir 600 mg BID + RTV 100 mg BID + OBR\*
  - Lopinavir/ritonavir (400/100 mg) BID + OBR\*

Darunavir 600 mg BID + Ritonavir 100 mg BID + OBR (n = 298)

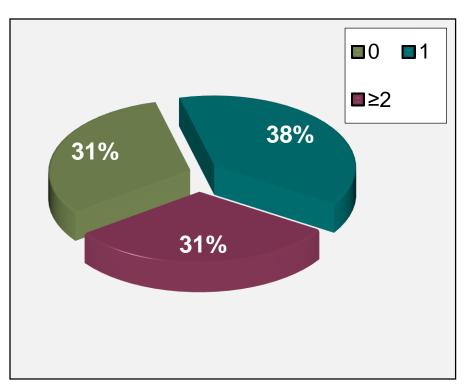
Lopinavir/ritonavir 400/100 mg BID + OBR (n = 297)

**TITAN** = <u>T</u>MC114/r <u>In</u> <u>T</u>reatment-experienced p<u>A</u>tients <u>N</u>aïve to lopinavir \*OBR = Optimized background regimen: ≥2 active antiretroviral agents

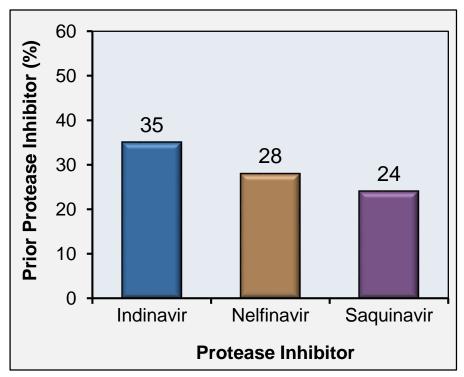


# Darunavir/r versus Lopinavir/r in Treatment-Experienced TITAN: Study Participant ARV Treatment History

#### **Prior Number of Protease Inhibitors**



#### **Most Frequently Used Prior Pls**

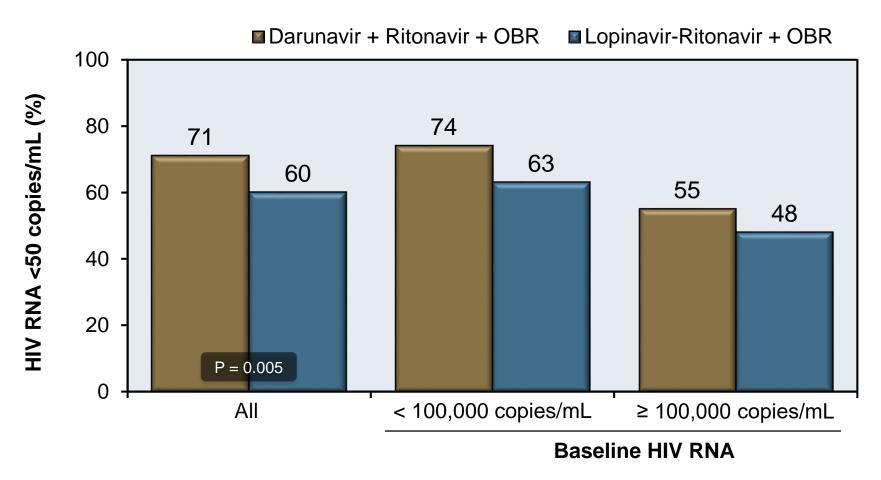




**Source: Madruga JV, et al. Lancet. 2007;370:49-58.** 

### Darunavir/r versus Lopinavir/r in Treatment-Experienced TITAN: Result

Week 48: Virologic Response (ITT-TLOVR)

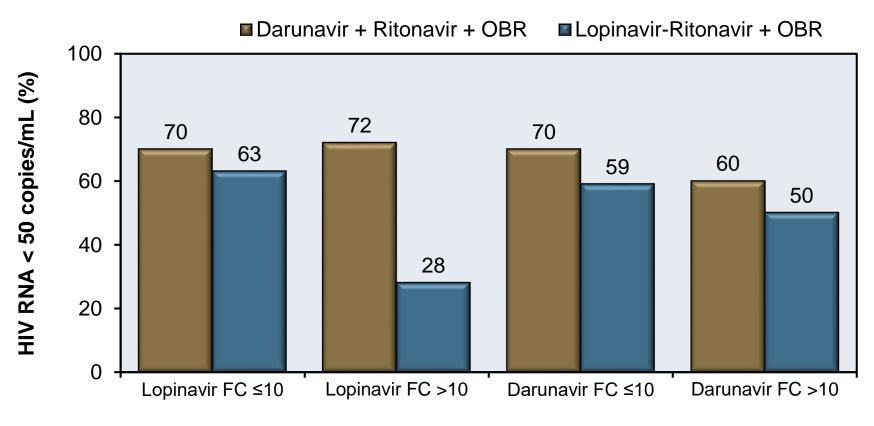




Source: Madruga JV, et al. Lancet. 2007;370:49-58.

## Darunavir/r versus Lopinavir/r in Treatment-Experienced TITAN: Result

Week 48: Virologic Response, by Baseline PI Resistance (ITT-TLOVR)



**Baseline Resistance** 



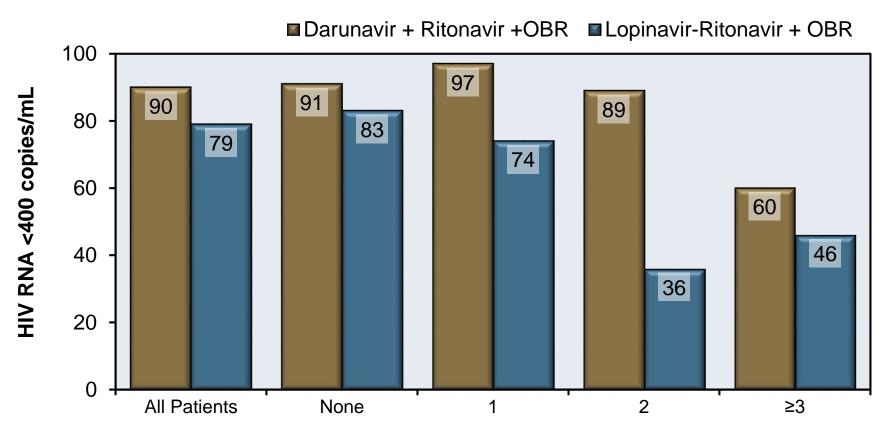
### Darunavir/r versus Lopinavir/r in Treatment-Experienced TITAN: Conclusions

Interpretation: "In lopinavir-naïve, treatment-experienced patients, darunavir-ritonavir was non-inferior to lopinavir-ritonavir treatment in terms of our virological endpoint, and should therefore be considered as a treatment option for this population."



# Darunavir/r versus Lopinavir/r in Treatment-Experienced TITAN (Characterization of Virologic Failure): Result

Week 48: Virologic Response, by Baseline Darunavir-Associated RAMs



**Number of Baseline Darunavir-Associated Mutations** 



Source: De Meyer S, et al. AIDS. 2009;23:1829-40.

### Darunavir/r versus Lopinavir/r in Treatment-Experienced TITAN (Characterization of Virologic Failure): Conclusions

**Conclusion**: "In treatment-experienced, LPV-naive patients, the overall virologic failure rate in the DRV/r arm was low and was associated with limited resistance development. These findings showed that the use of DRV/r in earlier lines of treatment was less likely to lead to cross-resistance to other protease inhibitors compared with LPV/r."



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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.



