

Cobicistat-Boosted PIs in Patients with Renal Impairment  
**Study 118**

# Cobicistat-Boosted PIs in Patients with Renal Impairment

## Study 118: Design

- **Background:** Phase 3, non-comparative, open label, 2 cohort study to compare the safety and efficacy of switching ritonavir to cobicistat in virologically suppressed adults with HIV infection and mild to moderate renal impairment
- **Inclusion Criteria (n = 73)\***
  - Antiretroviral treatment-experienced
  - HIV RNA undetectable x 6 months
  - On regimen of 2 NRTIs + ATV/r or DRV/r
  - Stable renal function with CrCl 50 to 89 mL/min
- **Treatment Arms**
  - Cobicistat 150 mg QD + [Atazanavir 300 mg QD or Darunavir 800 mg QD] + 2 NRTIs

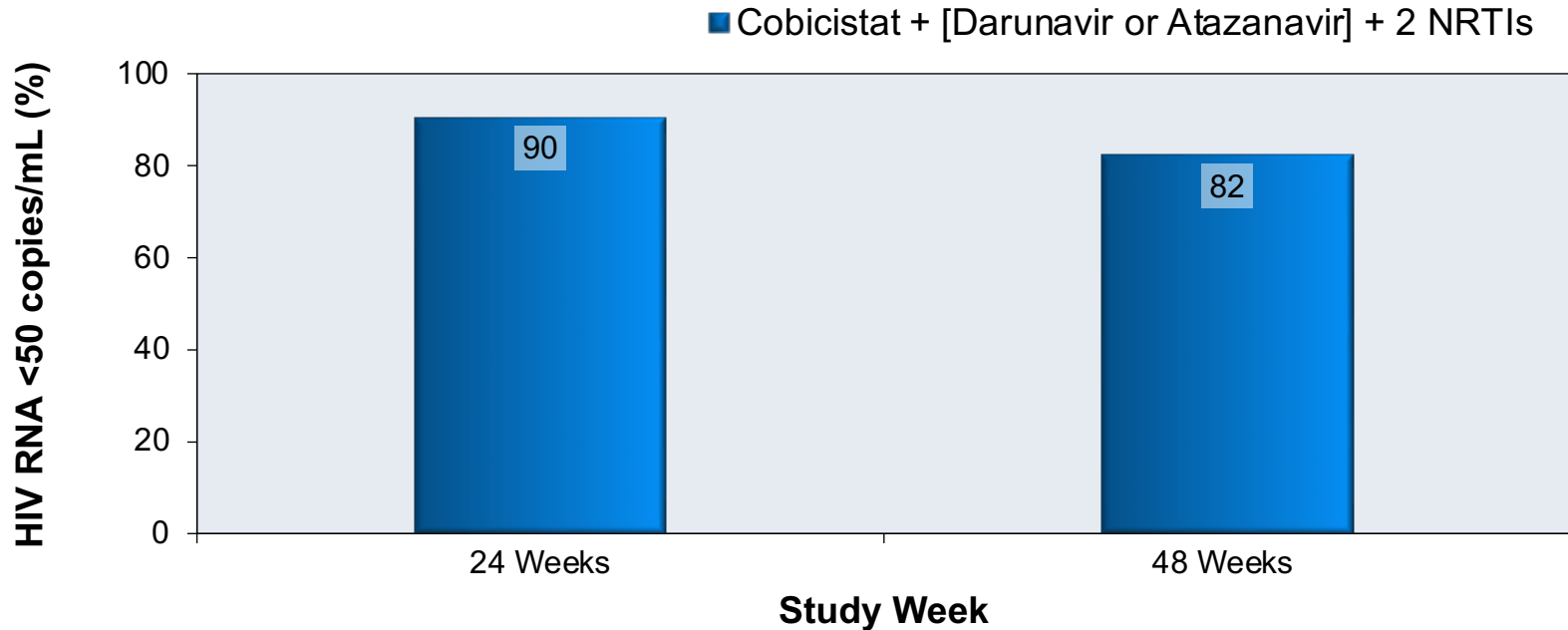


**Cobicistat +  
Atazanavir or Darunavir  
+ 2 NRTIs  
(n = 73)**

\*Note: only ritonavir-to-cobicistat switch cohort presented here

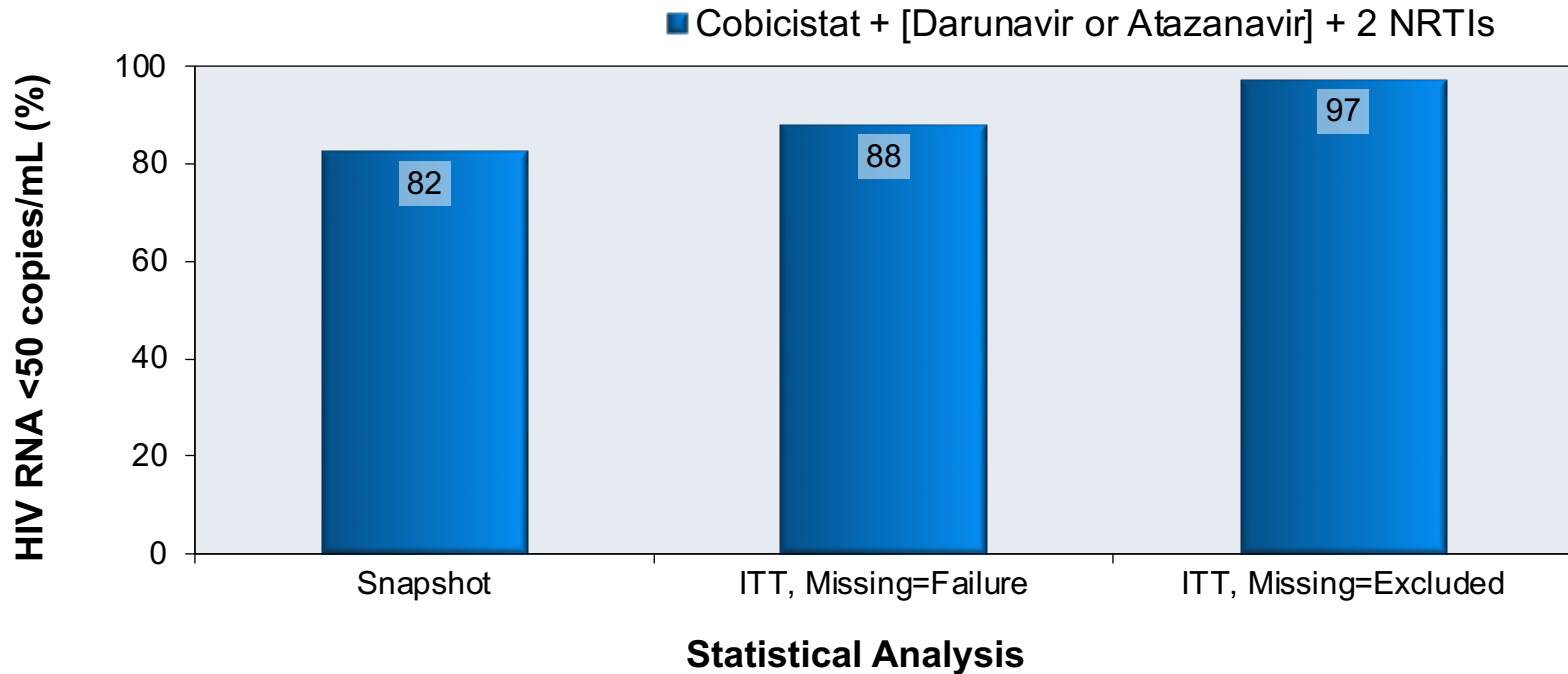
# Cobicistat-Boosted PIs in Patients with Renal Impairment Study 118: Results3

Week 24 and 48: Virologic Response (Snapshot Analysis)



# Cobicistat-Boosted PIs in Patients with Renal Impairment Study 118: Results

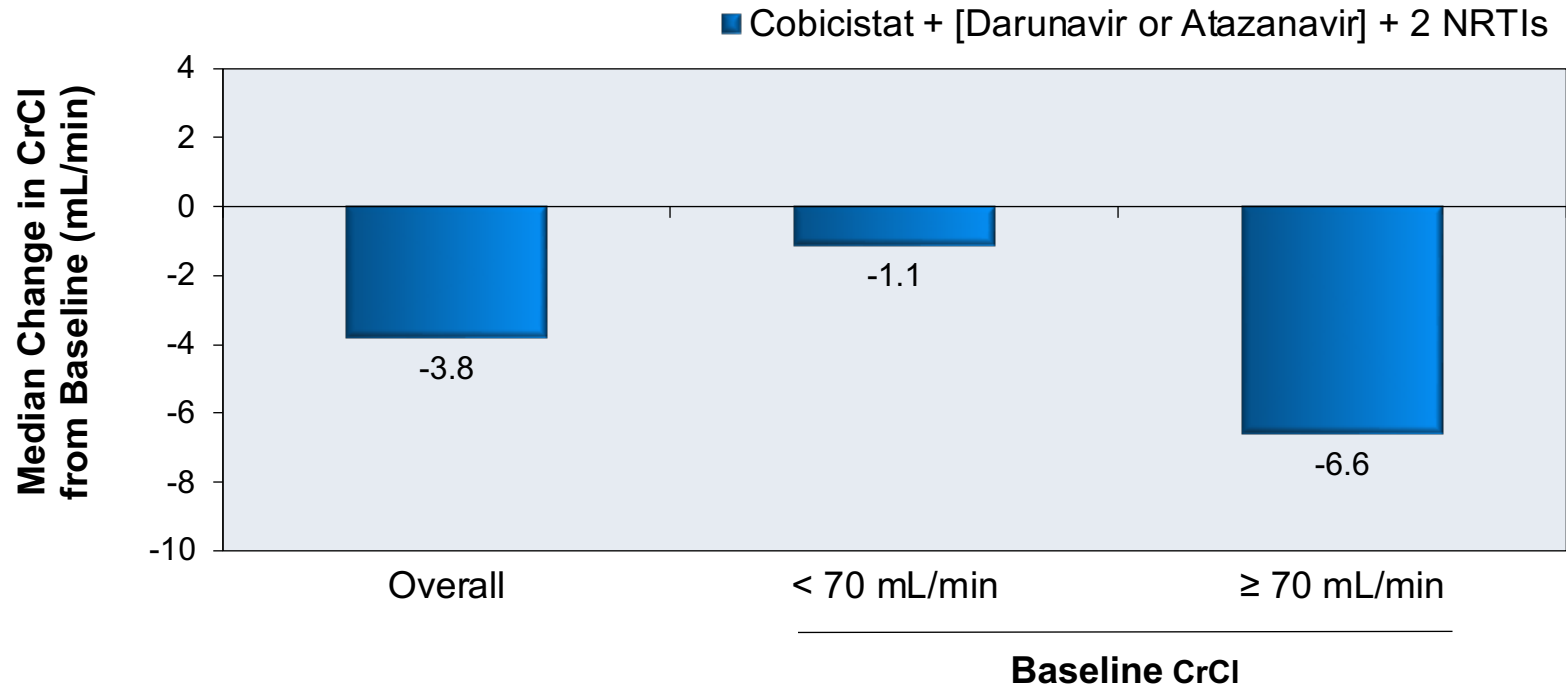
Week 48: Virologic Response, by Different Statistical Analyses



# Cobicistat-Boosted PIs in Patients with Renal Impairment

## Study 118: Results

Week 48: Changes in Creatinine Clearance, by Baseline CrCl



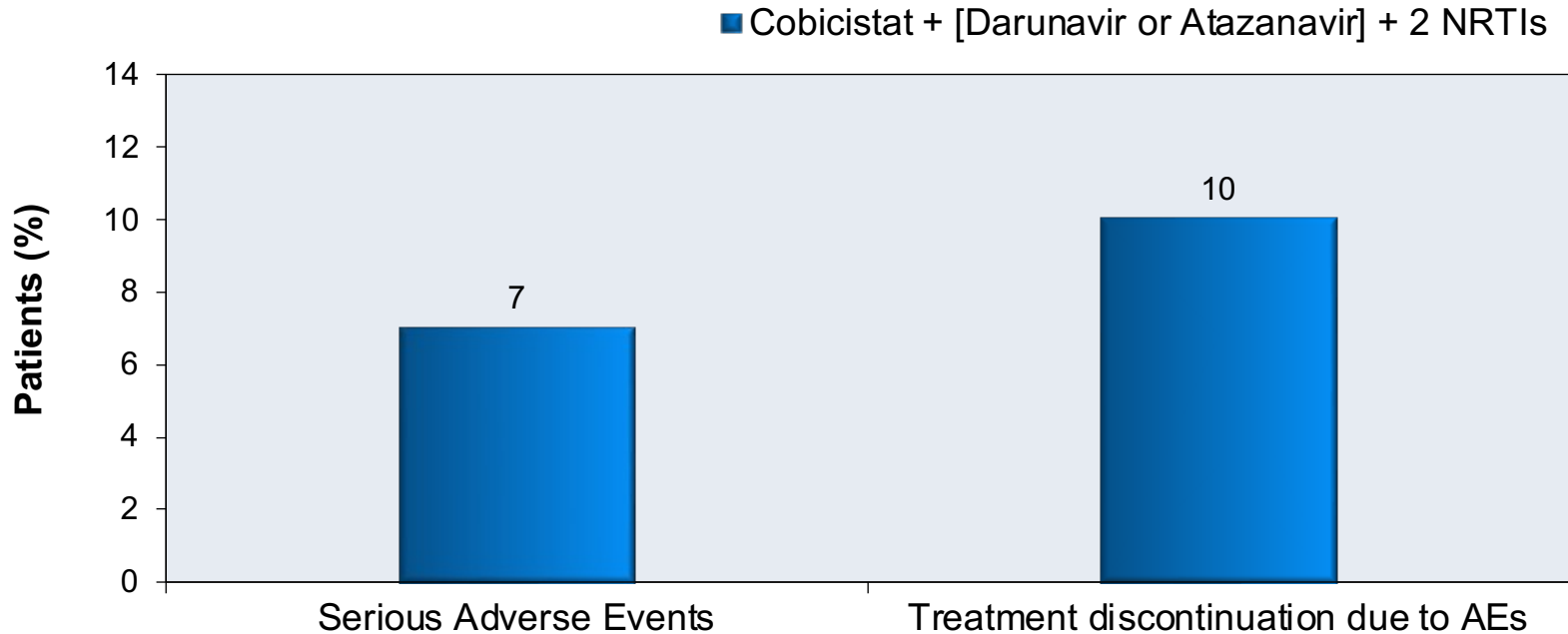
# Cobicistat-Boosted PIs in Patients with Renal Impairment

## Study 118: Results

Confirmed Renal Laboratory Abnormalities	
Laboratory Value	Cobicistat + [ATV or DRV] + 2 NRTIs (n=73)
Serum creatinine increase $\geq$ 0.4mg/dL	4.1%
Hypophosphatemia ( $\geq$ grade 1 increase)	1.4%
Proteinuria ( $\geq$ grade 2 increase)	1.4%
Normoglycemic glycosuria ( $\geq$ grade 1 increase)	0

# Cobicistat-Boosted PIs in Patients with Renal Impairment Study 118: Results

## Adverse Events and Treatment Discontinuations



# Cobicistat-Boosted PIs in Patients with Renal Impairment

## Study 118: Conclusions

**Conclusions:** “COBI was noninferior to RTV in combination with ATV plus FTC/TDF at week 48. Both regimens achieved high rates of virologic success. Safety and tolerability profiles of the 2 regimens were comparable. Once-daily COBI is a safe and effective pharmacoenhancer of the protease inhibitor ATV.”



# Acknowledgments

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