

# ARV Therapies and Therapeutic Strategies

REPORTING ON CROI 2015

## Comprehensive Expert Review and Discussion of Key Presentations

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### Rosuvastatin Arrests Progression of Carotid Intima-Media Thickness in Treated HIV

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Abstract 137

## SATURN-HIV Design

### Inclusion

- HIV-1 & ≥18 years
- On ART >6mo & HIV-1 RNA ≤1000 cps/ml
- Fasting LDL-C ≤130mg/dl
- Heightened immune activation (CD8+CD38+DR+ ≥19% or hsCRP ≥2µg/ml)
- No CVD or diabetes
- No fragility fractures
- No immunomodulatory, bone tx, or hypolipemics

Rosuvastatin  
N=72

Stratified by:  
•PI vs not  
•Osteopenia vs not  
•CAC vs not

Placebo  
N=75

### Endpoints

- Cardiovascular
  - Carotid IMT (by US)
  - Coronary artery calcium score (by CT)
- CVD risk
  - Systemic & vascular inflammation
  - Lymphocyte & monocyte activation
  - Lipids
  - Insulin resistance

Week 0

Week 48

Week 96

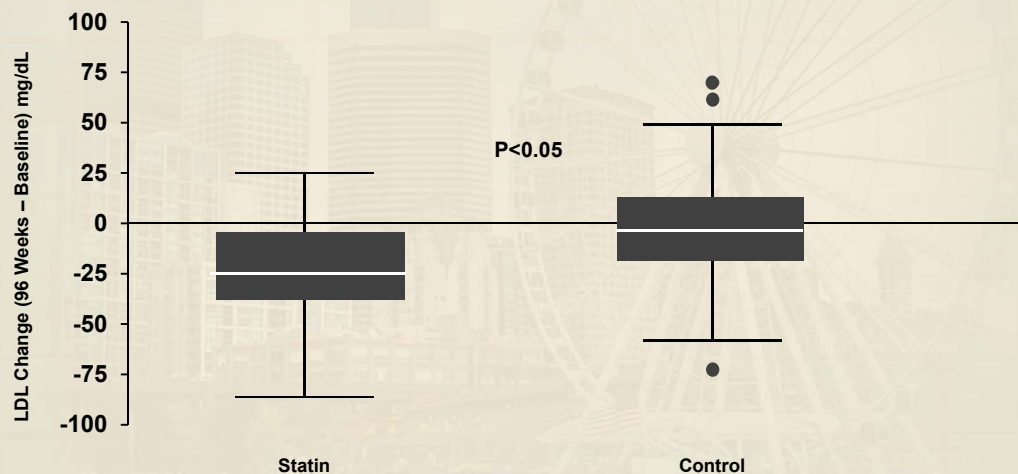
## Baseline Characteristics

	Statin n=72	Placebo n=75
Age years, median (IQR)	46 (41, 51)	47 (39,54)
Male (%)	81%	76%
White race (%)	28%	31%
Smoking (%)	60%	72%
BMI, median (IQR)	27 (23, 30)	27 (24, 31)
Using PI at entry (%)	50%	48%
HIV-1 RNA <50 copies/mL (%)	78%	77%
CD4 cells/mm <sup>3</sup> , median (IQR)	<b>608 (440, 848)</b>	<b>627 (398, 853)</b>
LDL-cholesterol mg/dL, median (IQR)	<b>96 (76, 107)</b>	<b>97 (77, 121)</b>
Mean CCA IMT mm, Median (IQR)	0.664 (0.624, 0.772)	0.670 (0.602, 0.752)
% with carotid plaque	33%	43%
% with CAC =0	67%	60%
CAC (among CAC>0), median (IQR)	30 (8, 88)	51 (6, 127)

\* Well balanced between arms

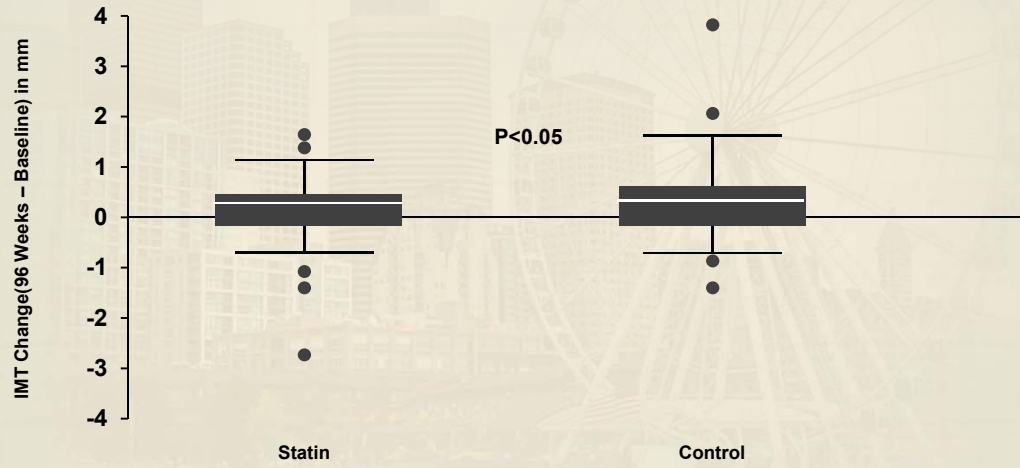
Longenecker C, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 137.

## Change in LDL-Cholesterol (ITT)



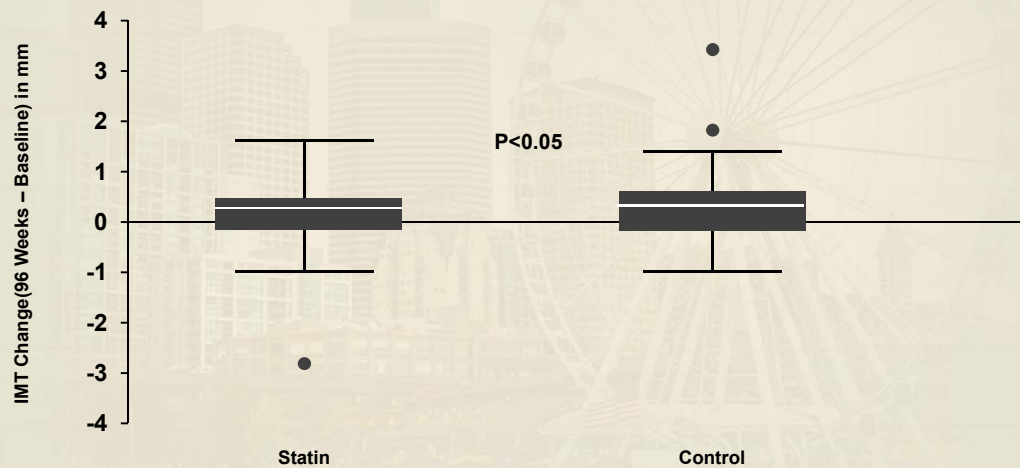
Longenecker C, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 137.

## Change in Mean CCA IMT (ITT)



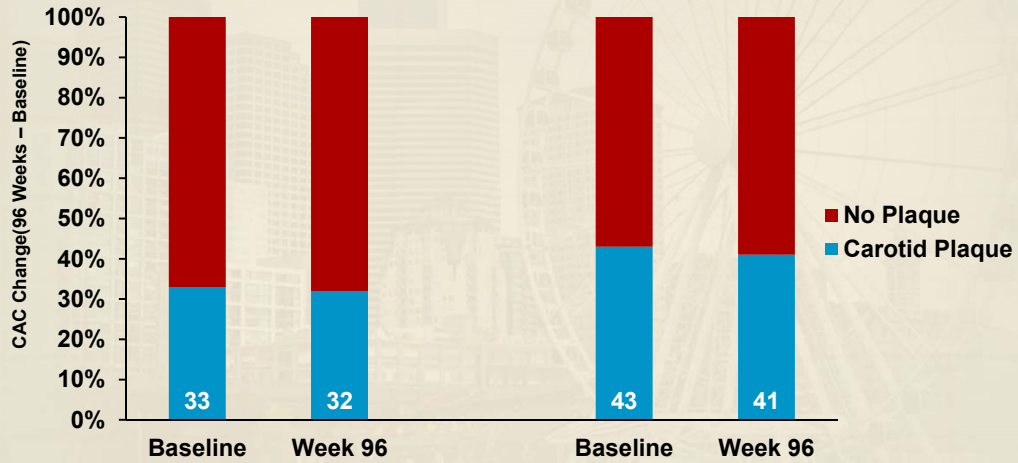
Longenecker C, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 137.

## Change in Mean CCA IMT in Subset with Baseline CAC



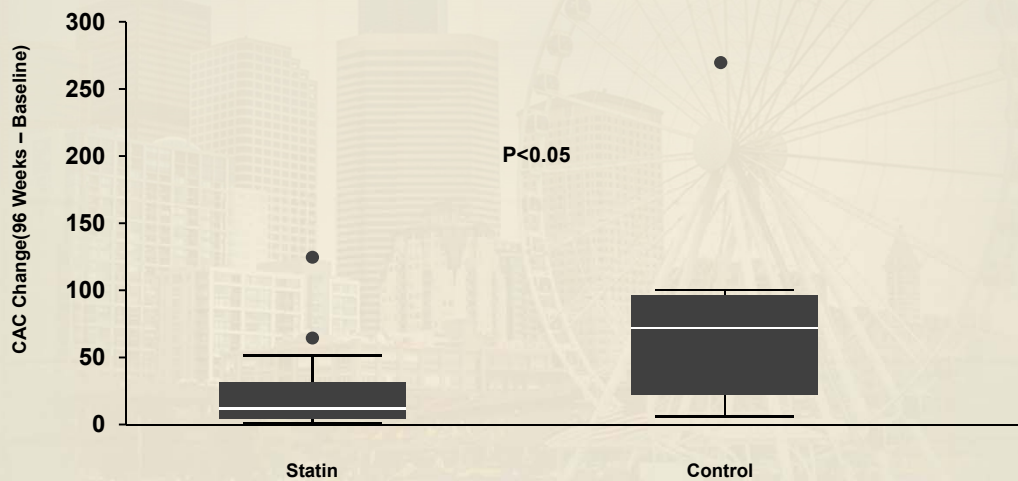
Longenecker C, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 137.

## No Change in Prevalence of Carotid Plaques by Study Arms



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## Change in CAC Score in the Subset with CAC at Baseline



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## Predictors of Change in CCA IMT

- Changes in IMT were independent of PI use and baseline or changes in LDL-C, HOMA-IR, CD4 count, CRP or T-cell activation
- Higher baseline CCA IMT, IL-6 levels, and %CD14dimCD16+ (patrolling monocytes) are associated with larger decline in IMT

Longenecker C, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 137.

## Conclusions

- In HIV-infected subjects on ART with LDL-C < 130 mg/dL, rosuvastatin arrests IMT progression
- Changes in IMT were independent of PI use, changes in lipids or insulin resistance
- The favorable effect on IMT appears to be more pronounced in subjects with underlying coronary calcifications at baseline
- In subjects with baseline coronary calcifications, rosuvastatin halts the progression of CAC

Longenecker C, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 137.