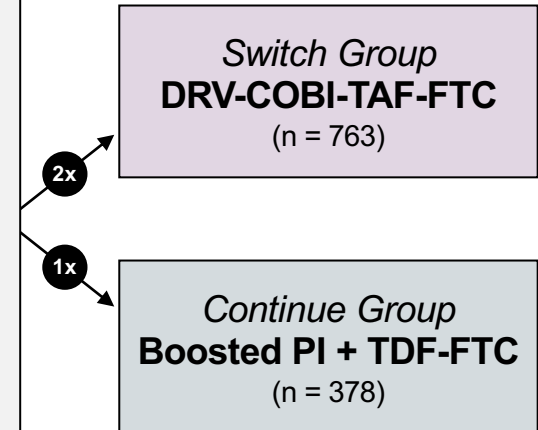


DRV-COBI-TAF-FTC vs Continue Boosted PI + TDF-FTC  
**EMERALD**

# DRV-COBI-TAF-FTC vs Continue Boosted PI + TDF-FTC

## EMERALD: Design

- **Background:** Randomized, open-label, active-controlled, international, phase 3 study evaluating the efficacy and safety of switching to the single-tablet regimen DRV-COBI-TAF-FTC versus continuing a boosted PI + TDF-FTC
- **Inclusion Criteria (n = 1,141)**
  - Age  $\geq 18$  years
  - Antiretroviral experienced
  - HIV RNA  $\leq 50$  copies/mL for  $>2$  months\*
  - Taking a PI plus ritonavir or cobicistat
  - Regimen stable for  $\geq 6$  months
  - eGFR  $\geq 50$  mL/min
  - No prior virologic failure on a DRV-based regimen
  - Virologic failure on non-DRV-based regimen allowed
  - Not pregnant or breastfeeding



\*One HIV RNA 50-200 copies/mL within prior 12 months allowed

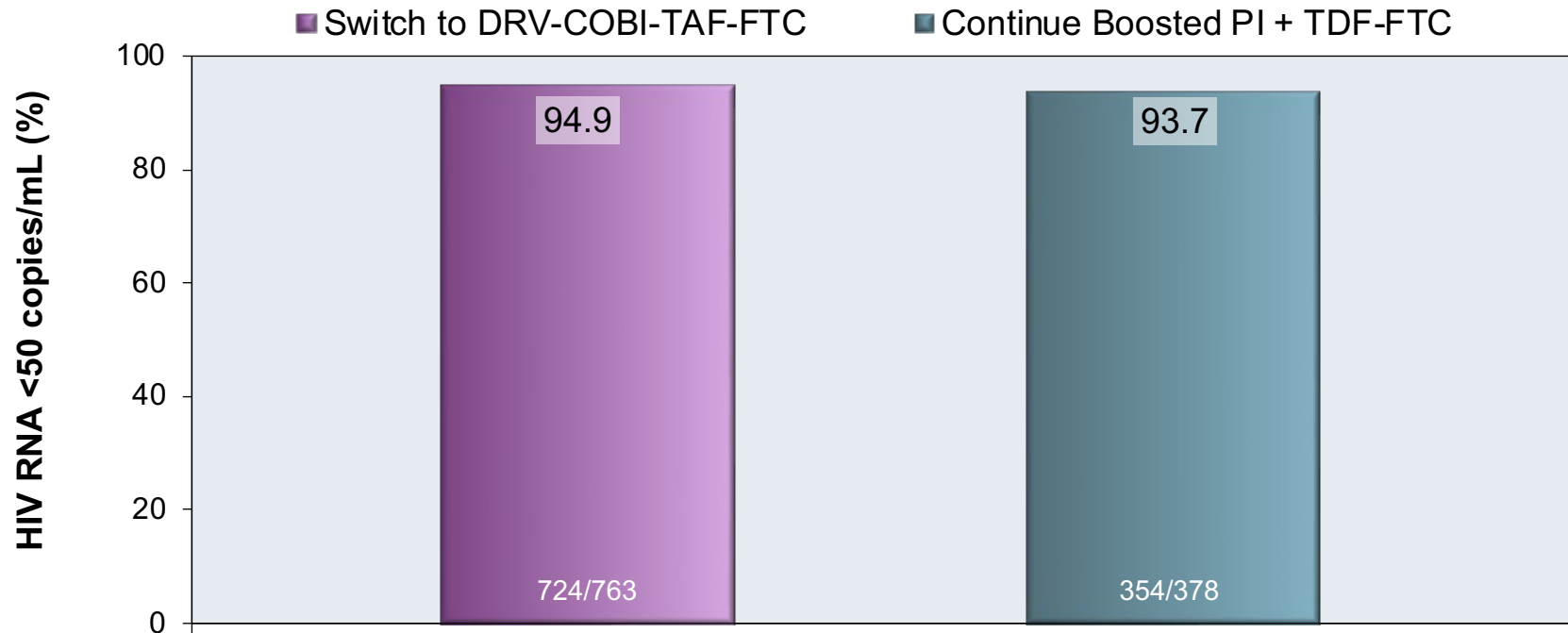
# DRV-COBI-TAF-FTC vs Continue a Boosted PI + TDF-FTC

## EMERALD: Baseline Characteristics

EMERALD Study: Baseline Characteristics		
	DRV-COBI-TAF-FTC Switch Group (n = 763)	Boosted PI + TDF-FTC Continue Group (n = 378)
CD4 Count (cells/mL)	630	624
Time since HIV diagnosis (years)	9.3	8.9
Time since first ART (years)	6.2	5.8
Previous use of >5 ARV's	59	58
Previous virologic failure	15	14
Boosted darunavir at screening (%)	70	70
Boosted atazanavir at screening (%)	22	22
Boosted lopinavir at screening (%)	8	8

# DRV-COBI-TAF-FTC vs Continue a Boosted PI + TDF-FTC EMERALD: Results

Week 48: Virologic Response by FDA Snapshot Analysis, ITT



Source: Orkin C, et al. Lancet HIV. 2018;5:e23-e34.

# DRV-COBI-TAF-FTC vs Continue a Boosted PI + TDF-FTC EMERALD: Results

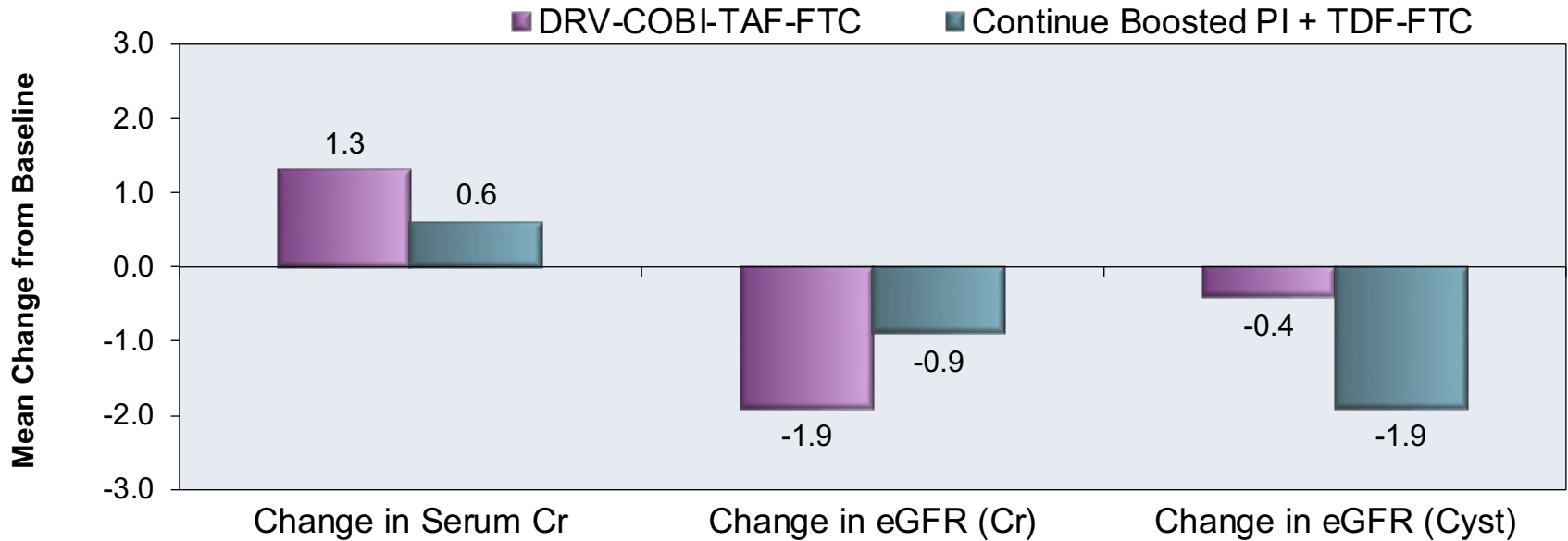
## Week 48: Virologic Outcomes

EMERALD Study Virologic Outcomes		
	DRV-COBI-TAF-FTC <i>Switch Group</i> (n = 763)	Boosted PI + TDF-FTC <i>Continue Group</i> (n = 378)
Virologic rebound rate through 48 weeks*	2.5%	2.1%
HIV RNA <50 copies/mL at 48 weeks	94.9%	93.7%
HIV RNA $\geq$ 50 copies/mL at 48 weeks	0.8%	0.5%
No virologic data at 48 weeks	4.3%	5.8%

\*HIV RNA  $\geq$ 50 copies/mL or premature discontinuation with last HIV RNA  $\geq$ 50copies/mL

# DRV-COBI-TAF-FTC vs Continue a Boosted PI + TDF-FTC EMERALD: Results

Week 48: Change in Serum Creatinine and Estimated GFR



Cr = creatinine (measured in  $\mu\text{mol/L}$ )

eGFR = estimated glomerular filtration rate (measured in  $\text{mL/min}/1.73 \text{ m}^2$ , calculated using CKD-EPI)

Cyst = cystatin C

# DRV-COBI-TAF-FTC vs Continue a Boosted PI + TDF-FTC EMERALD: Results

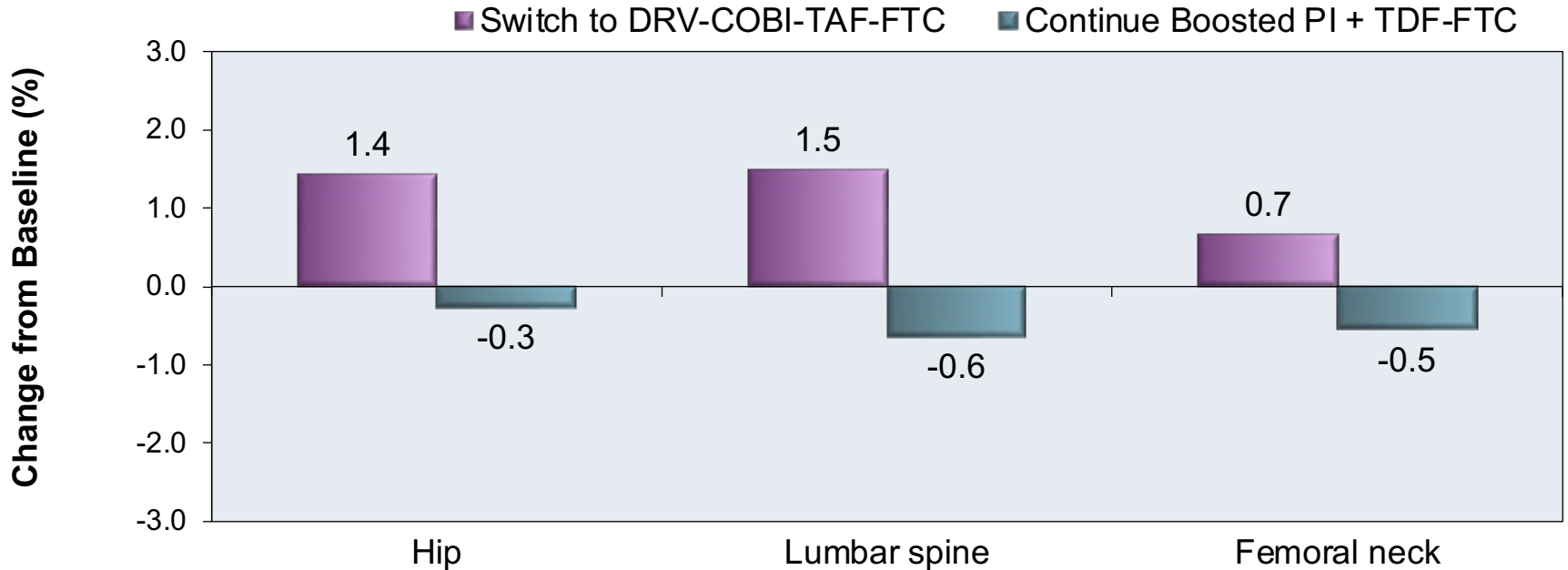
Week 48: Change in Urinary Markers of Tubular Dysfunction

Mean Change in Markers of Proximal Tubulopathy at Week 48		
	DRV-COBI-FTC-TAF <i>Switch Group</i> (n = 763)	Boosted PI + TDF-FTC <i>Continue Group</i> (n = 378)
UPCR (mg/g)	-33.9	-6.43
UACR (mg/g)	-3.2	1.3
RBP:Cr (mg/g)	-630.5	1037.1
$\beta$ 2M:Cr (mg/g)	-1454.7	1371.3

UPCR = urine protein to creatinine ratio; UACR = urine albumin to creatinine ratio  
RBP:Cr = retinol binding protein to creatinine ratio;  $\beta$ 2M:Cr = beta-2-microglobulin to creatinine ratio

# DRV-COBI-TAF-FTC vs Continue a Boosted PI + TDF-FTC EMERALD: Results

Week 48: Change in Bone Mineral Density



This is from a bone mineral density substudy (n = 209 participants in switch arm, 108 in control arm)



# DRV-COBI-TAF-FTC vs Continue a Boosted PI + TDF-FTC EMERALD: Results

Median Change in Fasting Lipid Parameters at Week 48		
	DRV-COBI-FTC-TAF Switch Group (n = 763)	Boosted PI + TDF-FTC Control Group (n = 378)
TC (mg/dL)	19.7	1.3
LDL (mg/dL)	15.7	1.9
HDL (mg/dL)	3.0	-1.0
TC:HDL ratio	0.2	0.1
Triglycerides (mg/dL)	6.0	5.0

TC = total cholesterol; LDL = low density lipoprotein; HDL = high density lipoprotein

# DRV-COBI-TAF-FTC vs Continue a Boosted PI + TDF-FTC EMERALD: Conclusions

**Conclusions:** “Our findings show the safety and efficacy of single-tablet darunavir, cobicistat, emtricitabine, and tenofovir alafenamide as a potential switch option for the treatment of HIV-1 infection in adults with viral suppression.”

# Acknowledgments

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