Measuring Safety and Satisfaction of ABC/DTG/3TC in a Switch Trial: Secondary Endpoints from the STRIIVING Study

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Abstract LBPS10/1

STRIIVING Study Design

Countries: US, Canada, Puerto Rico

Open-label, Randomized 1:1

- **ABC/DTG/3TC**
- **Current ART*** → **ABC/DTG/3TC**

Screening 0 — **w24** — **w48**

Primary endpoint at 24 weeks: VL <50 c/mL (Snapshot)

Inclusion Criteria
Virologically suppressed (confirmed HIV-1 RNA <50 c/mL)
HLA-B*5701 negative

Assessments
CD4 cell count changes
Clinical and laboratory safety
Lipids, renal, bone, and cardiovascular changes
Development of resistance
Treatment satisfaction

*Stable suppressive current ART with 2 NRTIs plus either a PI, an NNRTI, or an INI. ≥40% PIs, at least 25% INIs. 90% power based on 10% non-inferiority margin (estimated response rate = 85%).

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Baseline Characteristics

	ABC/DTG/3TC (n=274)	CAR (n=277)	Total (N=551)
Age (years), median	45	47	45
Female	14%	14%	14%
African American/African heritage	30%	27%	28%
HBV/HCV positive	0%,8%	0%,5%	0%,7%
CDC class C	15%	16%	15%
CD4+ (cells/mm^3), median	618	597	610
<500	30%	33%	31%
≥500	70%	67%	69%
Time on ART (median)	55 months	51 months	52 months
Baseline HIV TSQ Score (mean)	53.0	53.4	53.2
Current ART at screening			
PI	43%	42%	42%
NNRTI	31%	31%	31%
INI	26%	27%	26%
TDF/FTC backbone	76%	79%	77%

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STRIIVING: Adverse Events

	ABC/DTG/3TC (n=275)	CAR (n=276)
Any adverse event	180 (65%)	124 (45%)
Grade 3 and 4 AE	8 (3%)	5 (2%)
Serious AE	6 (2%)	5 (2%)
Discontinuations due to AEs	10 (4%)	0
Adverse events occurring in at least 5% of participants in either group		
Cough	14 (5%)	8 (3%)
Diarrhoea	20 (7%)	4 (1%)
Fatigue	19 (7%)	3 (1%)
Headache	13 (5%)	4 (1%)
Nausea	27 (10%)	3 (1%)
Upper respiratory tract infection	20 (7%)	20 (7%)

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Study Disposition: Week 24

Screened (N=841)

Randomized and treated ABC/DTG/3TC (n=274)

87% completed W24 (n=239)

13% of subjects withdrawn (n=35)

Adverse event	10 (4%)
Lack of efficacy (virologic failure)	0
Protocol deviation	15 (5%)
Stopping criteria met	0
Lost to follow-up	3 (1%)
Investigator discretion	3 (1%)
Withdrew consent	4 (1%)

Randomized and treated CAR (n=277)

88% completed W24 (n=245)

12% of subjects withdrawn (n=32)

Adverse event	0
Lack of efficacy (virologic failure)	0
Protocol deviation	17 (6%)
Stopping criteria met	0
Lost to follow-up	3 (1%)
Investigator discretion	3 (1%)
Withdrew consent	9 (3%)

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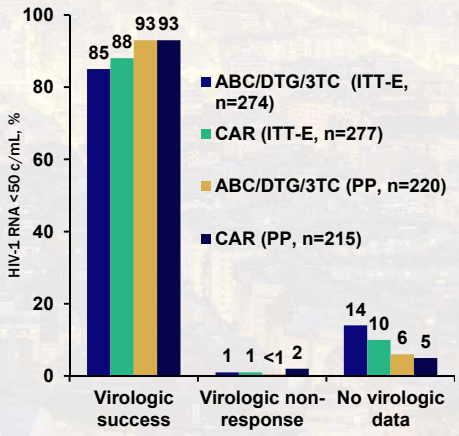
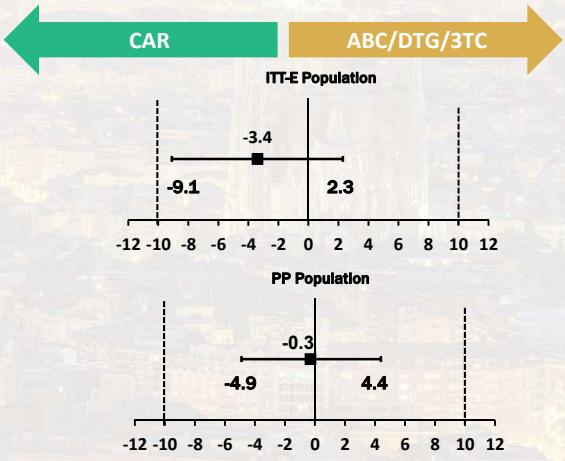
STRIIVING Study: Snapshot Outcomes at Week 24

Virologic outcomes



Treatment differences (95% CI)



CI, confidence interval; ITT-E, intent-to-treat exposed; PP, per protocol.

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Virologic Endpoints

No subjects met protocol-defined virologic failure in either study arm

	ABC/DTG/3TC (n=274)	CAR (n=277)
PDVF	0	0
VL ≥50 in W24 window	3 (1%)*	4(1%)**

- Subjects with HIV-1 RNA ≥50 c/mL at any visit (scheduled or unscheduled) will require further testing
- Subjects with HIV-1 RNA ≥400 c/mL on 2 consecutive assessments any time after randomization are withdrawn = meets "confirmed virologic withdrawal criterion"

*ABC/DTG/3TC: VLs : 58, 64, 71 c/mL
**CAR VLs: 55, 55, 61, 85 c/mL

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AEs Among 10 Participants Who Withdrew

Subject	AE Term(s)[1]	Grade	Onset	3rd Agent
1	Insomnia	2	Week 1	LPV/r
2	Diarrhea, flatulence, rash Abdominal pain, anxiety, nausea, body ache	1 2	Week 1 Week 1	RPV
3	Euphoric mood Headache	1 2	Week 1	ATV/r
4	Abdominal cramps, chills, diarrhea, dizziness, headache	2	Week 1	RAL
5	Pruritus	2	Week 1	NFV
6	Abdominal pain upper, diarrhea Fatigue, malaise Flu-like syndrome Depression Profuse sweating, change in body odor	1 2 1 2 1	Week 1 Week 1 Week 9 Week 12 Week 17	NVP
7	Nasal congestion Worsening fatigue Nausea	1 2 3	Week 2	EVG/c
8	Alopecia	1	Week 4	ATV/r
9	Fatigue[2]	1	Week 8	DRV/r
10	Homicide[2]	N/A	Week 10	RAL

1 None of the events were SAEs, except homicide.
2 These events were not drug related.

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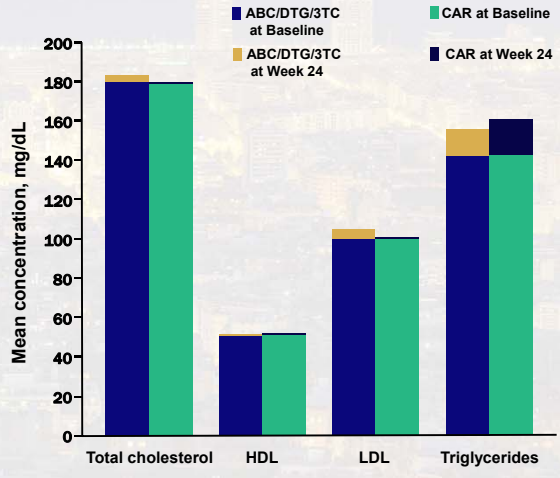
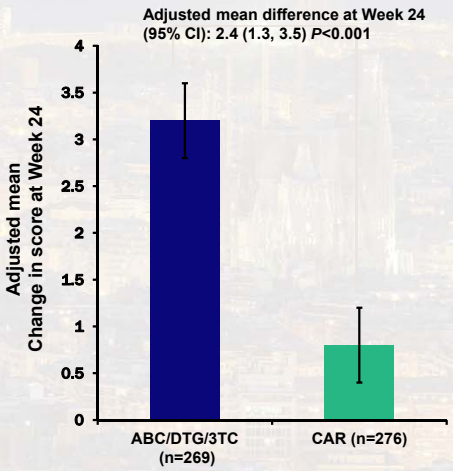
STRIIVING Study: Change From Baseline in Fasting Lipids and Patient Satisfaction





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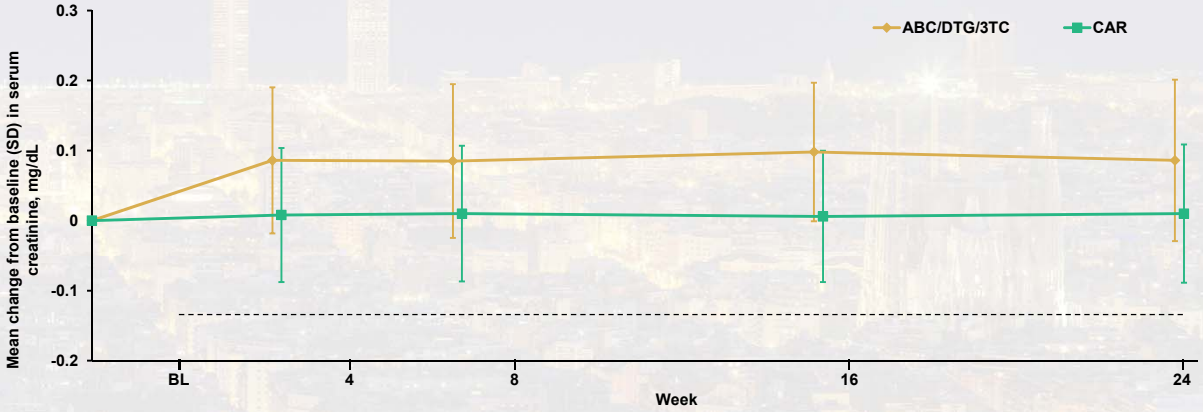
Mean Change From Baseline in Serum Creatinine Through 24 Weeks



	BL	4	8	16	24
Number of patients					
ABC/DTG/3TC	275	262	256	237	240
CAR	276	257	257	246	249

- Small, non-progressive changes in serum creatinine were observed in the ABC/DTG/3TC arm due to known inhibition of tubular creatinine secretion by DTG

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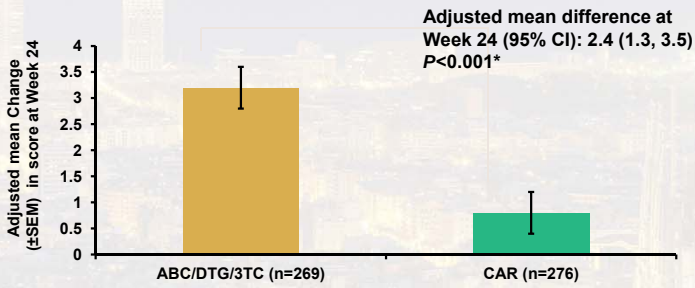
Greater Improvements in ABC/DTG/3TC Arm: Overall Treatment Satisfaction



- At baseline, overall treatment satisfaction scores were similar between groups
- HIV TSQ total scores increased in both groups, with a statistically significant difference favoring ABC/DTG/3TC

*P-values based on ANCOVA model with factors including treatment, baseline score and stratification factor.
SEM, standard error of adjusted mean; TSQ, treatment satisfaction questionnaire.

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