Switch to Bictegravir-Tenofovir alafenamide-Emtricitabine for Black Americans **BRAAVE2020**



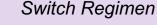
Switch to Bictegravir-TAF-FTC for Black Americans BRAAVE2020: Design

Background

 Randomized, phase 3, multicenter, open-label switch study evaluating the efficacy and safety of switching Black American adults with viral suppression to BIC-TAF-FTC, including individuals with a history of NRTI, NNRTI, and/or PI resistance

Inclusion Criteria

- Age ≥18 years
- Self-described as Black, African American, or mixed race that includes Black
- HIV RNA <50 copies/mL for ≥12 months
- Taking stable antiretroviral regimen that includes 2 NRTIs plus 3rd agent for ≥6 months
- eGFR ≥50 mL/min
- No INSTI resistance; no K65R, T69ins, or ≥3TAMs



Bictegravir-TAF-FTC

(n = 328)



Maintain Regimen

Continue baseline ART

(n = 165)

10% of all participants with M184V at baseline



Switch to Bictegravir-TAF-FTC for Black Americans BRAAVE2020: Baseline Characteristics

BRAAVE2020 Baseline Participant Demographics & Clinical Characteristics		
Baseline Characteristic	BIC-TAF-FTC (n = 328)	Continue Baseline ART (n = 165)
Age, years, median (range)	49 (18-79)	49 (19-70)
Female sex at birth, n (%)	101 (31)	55 (33)
Cisgender, n (%)	317 (96)	159 (96)
Hispanic or Latino, n (%)	61 (22%)	49 (18%)
CD4 cell count, cells/µL, median (IQR)	747 (570-922)	758 (494-969)
TAF-FTC NRTI backbone, n (%)	224 (68)	107 (65)
TDF-FTC NRTI backbone, n (%)	56 (17)	34 (21)
ABC-3TC NRTI backbone, n (%)	44 (13)	24 (15)
Other NRTI backbone, n (%)	4 (1)	0



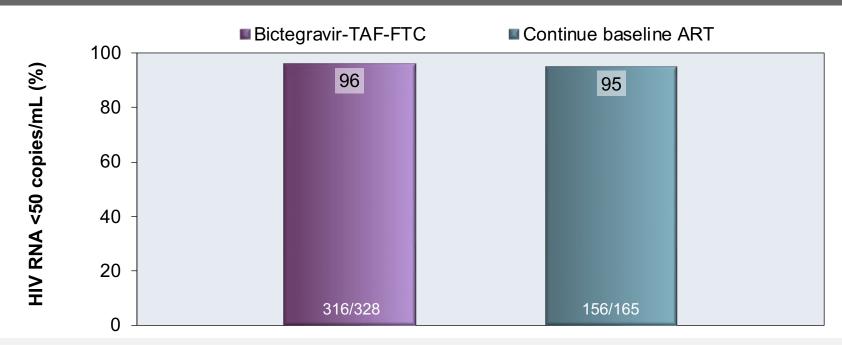
Switch to Bictegravir-TAF-FTC for Black Americans BRAAVE2020: Baseline Characteristics

BRAAVE2020 Baseline Participant Demographics & Clinical Characteristics		
Baseline Characteristic	BIC-TAF-FTC (n = 328)	Continue Baseline ART (n = 165)
Baseline 3 rd agent, n (%)		
INSTI	202 (61)	99 (60)
NNRTI	100 (30)	51 (31)
PI	30 (9)	14 (9)
CCR5 antagonist	0	1 (1)
Baseline ARV resistance, n (%)		
NRTI resistance	44 (13)	26 (16)
M184V/I	31 (9)	20 (12)
NNRTI resistance	70 (21)	32 (19)
PI resistance	36 (11)	26 (16)
INSTI resistance	8 (2)	3(2)

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Switch to Bictegravir-TAF-FTC for Black Americans BRAAVE2020: Results

Week 24 Virologic Response (Intention-to-Treat Analysis)

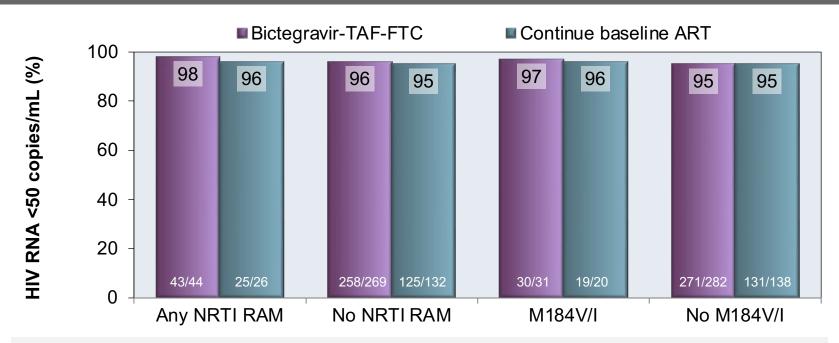


Primary outcome of HIV RNA ≥50 copies/mL at 24 weeks: 0.8% BIC-TAF-FTC arm; 1.6% continue baseline ART arm



Switch to Bictegravir-TAF-FTC for Black Americans BRAAVE2020: Results

Week 24 Virologic Response by Baseline Resistance (Intention-to-Treat Analysis)



RAM = resistance associated mutation



Switch to Bictegravir-TAF-FTC for Black Americans BRAAVE2020: Conclusions

Conclusions: "For Black Americans with HIV, switching to B/F/TAF was noninferior to continuing a variety of regimens, including those with pre-existing NRTI mutations."



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