Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression **GS-380-4030**



Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression GS-380-4030: Design

Background

 Randomized, double-blind, switch study comparing the efficacy of switching adults with viral suppression (with or without documented or suspected NRTI resistance) taking DTG plus TAF-FTC or TDF-FTC to BIC-TAF-FTC versus DTG plus TAF-FTC

Inclusion Criteria

- Age ≥18 years
- HIV RNA <50 copies/mL for 3 months if no resistance
- HIV RNA <50 copies/mL for 6 months if NRTI resistance
- Taking stable regimen of DTG plus TDF-FTC or TAF-FTC
- eGFR ≥30 mL/min
- Chronic HBV and HCV infection permitted
- Documented or suspected NRTI resistance permitted
- Excluded if integrase resistance or virologic failure on INSTI

Bictegravir-TAF-FTC

Dolutegravir + TAF-FTC (n = 281)



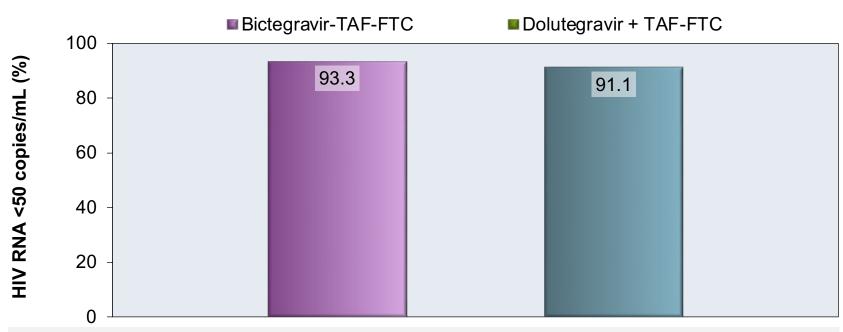
Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression GS-380-4030: Baseline Characteristics

Study GS-380-4030 Baseline Participant Demographics & Clinical Characteristics		
Baseline Characteristic	BIC-TAF-FTC (n = 284)	DTG + TAF-FTC (n = 281)
Age, years, median (range)	51 (22-79)	50 (20-79)
Women, n (%)	39 (14%)	41 (15%)
Black, n (%)	68 (24%)	61 (22%)
Hispanic or Latino, n (%)	61 (22%)	49 (18%)
CD4 cell count, cells/µL, median (IQR)	659 (486-885)	642 (462-791)
TAF-FTC NRTI backbone, n (%)	194 (68%)	195 (69%)
K65R/E/N or ≥3 TAMs mutation(s), n (%)	16 (6%)	14 (5%)
Any other pattern of NRTI mutation(s), n (%)	55 (19%)	53 (19%)
No NRTI mutation, n (%)	213 (75%)	214 (76%)



Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression GS-380-4030: Results

Virologic Outcome at Week 48



Primary outcome of HIV RNA ≥50 copies/mL at 48 weeks: 0.4% BIC-TAF-FTC arm; 1.1% DTG + TAF-FTC arm



Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression GS-380-4030: Conclusions

Interpretation: "The single-tablet regimen B/F/TAF is a safe, effective option for people virologically suppressed on DTG plus either F/TDF or F/TAF, including in individuals with preexisting resistance to NRTIs."



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