**Significant Efficacy and Long-term Safety Difference With TAF-Based STR in Naive Adults**

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**Introduction**

Two randomized, controlled, double-blind, multinational Phase 03 trials (Studies 104 [NCT01758098] and 111 [NCT01797445]) compared the NRTI-backbone disulfiram (TDF) and tenbloc disulfiram (TDF), each in single-tablet regimens coformulated with elvitegravir (E)/cobicistat (C)/emtricitabine (F) vs placebo.

**Results**

At Week 48 (primary endpoint) and 96, E/C/F/TAF had noninferior efficacy (HIV-1 RNA <50 copies/mL) to E/C/F/TDF, with no impact on bone and renal safety. 4 53

Emergence of resistance was rare. At Week 144, median change from baseline in eGFR CG was 0.0 vs 6 D/C for bone loss.

**Methods**

**Study Design**

- Two randomized, controlled, double-blind, multinational Phase 03 trials (Studies 104 [NCT01758098] and 111 [NCT01797445]) compared the NRTI-backbone disulfiram (TDF) and tenbloc disulfiram (TDF), each in single-tablet regimens coformulated with elvitegravir (E)/cobicistat (C)/emtricitabine (F)

**Week 144 Safety Summary**

- By 144 wk, virologic failure with resistance occurred in 24 participants (1.4% vs 12 (1.4%) on TDF)

**Week 144 Adverse Events Leading to Discontinuation**

- 0 case of proximal renal tubulopathy in E/C/F/TAF arm vs 4 in E/C/F/TDF arm

**Week 144 Grade 3 or 4 Laboratory Abnormalities**

- Most AEs occurred within first 4 wk of treatment initiation

**Week 144 Change from Baseline in Fasting Lipids**

- TC:HDL ratio was higher in TDF group

**Baseline Characteristics and Past Medical History**

- Participants on E/C/F/TAF had greater increases in TC, LDL, and HLD than those on E/C/F/TDF, with no difference in rate of initiation of lipid-modifying agents (E/C/F/TAF: 5.5% [n=49]; E/C/F/TDF: 5.8% [n=50])

**Renal Parameters Through Week 144**

- Through Week 144, significantly greater losses in spine and hip BMD in TDF group

**Renal Adverse Events Leading to Discontinuation**

- No D/C due to bone AEs in TAF arm vs 6 in TDF arm

**Week 144 Week 144 Week 144 Week 144**

- Median age, yrs (range) 33 (18–74) vs 35 (18–76)

**Prodrug Pharmacology: TAF vs TDF**

- TFV greater plasma stability

**Baseline Compliance**

- Participants on E/C/F/TAF had greater increases in TC, LDL, and HLD than those on E/C/F/TDF, with no difference in rate of initiation of lipid-modifying agents (E/C/F/TAF: 5.5% [n=49]; E/C/F/TDF: 5.8% [n=50])