Tenofovir disoproxil fumarate (TDF) has been associated with clinically significant renal and bone toxicity. A randomized controlled trial compared tafamidis (TAF), administered as part of a single-tablet, once daily regimen of elvitegravir, cobicistat, emtricitabine (FTC), and TAF (E/C/F/TAF), to TDF/TAF in HIV-1 infected patients, with stable GFR, and significant reductions in proteinuria, and improvements in proximal renal tubular function, and hip and spine BMD.

### Virologic Outcomes at Week 96
- 89% of patients (214/242) maintained HIV-1 viral load <50 copies/mL at Week 96.
- 10% (23/242), virologic data were not available.
- 13 patients discontinued due to adverse events (AEs)
- 10 discontinued for other reasons (e.g., withdrawal of consent, protocol violation, and 12 had HIV-1 RNA >1000 copies/mL.

### Safety Summary
- Upper respiratory tract infection (14%), diarrhea (13%), and arthralgia (13%) were the most common AEs.
- AEs, grades, and frequencies were similar in patients with baseline eGFR <60 mL/min.
- 12 patients (5%) discontinued study drug for AEs.
- 7 with non-AEs:
  - Diarrhea, malignant peripheral neuropathy, pruritus, dizziness.
  - Single renal disease progression.
- 5 for decreased eGFR,
- 1 for LFT elevation.

### Conclusions
- This is the first study of a single-tablet antiretroviral regimen in patients with eGFR of 30-69 mL/min.
- At Week 96, switching to E/C/F/TAF maintained viral suppression, and was associated with stable eGFR, reductions in proteinuria, and improvements in proximal renal tubular function, and hip and spine BMD.
- These data support the safety and efficacy of once-daily E/C/F/TAF in HIV-infected patients with eGFR of 30-69 mL/min without dose adjustment.