Supplementary tables and figures

## Table S1. Baseline demographic and clinical characteristics

| Characteristic | **E/C/F/TAF(n=159)** | **ATV+RTV and FTC/TDF(n=53)** |
| --- | --- | --- |
| Age (years) | 36 (30, 43) | 36 (31, 44) |
| Race |  |  |
| White | 65 (40.9%) | 16 (30.2%) |
| Black | 69 (43.4%) | 32 (60.4%) |
| Asian | 12 (7.5%) | 3 (5.7%) |
| Ethnicity |  |  |
| Hispanic or Latino | 15 (9.4%) | 3 (5.7%) |
| Body-mass index (kg/m2) | 25·0 (21·5, 29·4) | 24·8 (21·2, 32·1) |
| CD4 count (cells/μL) | 580 (477, 723) | 687 (522, 811) |
| Creatinine clearance by Cockcroft-Gault (CG) formula (mL/min) | 103·2 (84·0, 124·8) | 100·8 (81·9, 121·2) |
| Proteinuria by urinalysis (dipstick) |  |  |
| Grade 0 | 144 (90·6%) | 49 (92·5%) |
| Grade 1 | 15 (9·4%) | 3 (5·7%) |
| Grade 2 | 0 | 1 (1·9%) |
| HBV Surface Antigen Status |  |  |
| Positive | 5 (3·1%) | 0 |
| Negative | 154 (96·9%) | 52 (100%) |
| HCV Antibody Status |  |  |
| Positive | 14 (8·8%) | 4 (7·5%) |
| Negative | 145 (91·2%) | 48 (90·6%) |

Data are median (IQR) or n (%).

## Table S2. Adverse events

|  | **E/C/F/TAF(n=159)** | **ATV+RTV and FTC/TDF(n=53)** |
| --- | --- | --- |
| Any adverse event | 111 (69.8%) | 31 (58.5%) |
| Grade 3 or 4 adverse event | 10 (6.3%) | 1 (1.9%) |
| Serious adverse event | 12 (7.5%) | 3 (5.7%) |
| Study drug-related adverse event | 18 (11.3%) | 2 (3.8%) |
| Study drug-related serious adverse event | 0 | 0 |
| Any adverse event leading to study drug discontinuation\* | 1 (0.6%) | 1 (1.9%) |
| Adverse event ≥ 5% |  |  |
| Upper respiratory tract infection | 19 (11.9%) | 10 (18.9%) |
| Headache | 15 (9.4%) | 3 (5.7%) |
| Influenza | 11 (6.9%) | 1 (1.9%) |
| Back pain | 11 (6.9%) | 1 (1.9%) |
| Neuropathy peripheral | 9 (5.7%) | 7 (13.2%) |
| Nausea | 8 (5.0%) | 2 (3.8%) |
| Vulvovaginal candidiasis | 4 (2.5%) | 3 (5.7%) |
| Abdominal pain | 3 (1.9%) | 3 (5.7%) |

Data are n (%).

\*Adverse event leading to study drug discontinuations were confusional state (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide) and hepatitis (ritonavir-boosted atazanavir plus coformulated emtricitabine and tenofovir disoproxil fumarate)

## Table S3. Bone and Renal Safety Parameters

|  |  |  |  |
| --- | --- | --- | --- |
|  | E/C/F/TAF(n=159) | ATV+RTV and FTC/TDF(n=53) | P-value |
| Parameter  | n |  | n |  |
| Spine BMD, mean (95% CI) |
| Baseline | 100 | 1.00 (0.96, 1.03) | 35 | 0.98 (0.92, 1.03) | 0.56\* |
| Percentage change at week 48 | 93 | 2.82 (2.17, 3.47) | 29 | 0.00 (-1.29, 1.29) | <0.001\* |
| Hip BMD, mean (95% CI) |
| Baseline | 101 | 0.95 (0.92, 0.98) | 35 | 0.93 (0.89, 0.98) | 0.57\* |
| Percentage change at week 48 | 94 | 2.08 (1.40, 2.76) | 29 | 1.33 (0.10, 2.56) | 0.29\* |
| eGFR, median (IQR) |
| Baseline | 159 | 103.2 (84.0, 124.8) | 53 | 100.8 (81.9, 121.2) | 0.51† |
| Change at week 48 | 153 | 4.2 (-6.0, 13.6) | 42 | -1.8 (-8.4, 7.2) | 0.060† |
| RBP:Cr, median (IQR) |
| Baseline | 159 | 108.1 (63.4, 197.3) | 53 | 99.0 (71.8, 185.3) | 0.81† |
| Percentage change at week 48 | 153 | -33.6 (-54.6, 1.5) | 49 | 23.4 (-6.8, 93.3) | <0.001† |
| β2-microglobulin:Cr, median (IQR) |
| Baseline | 159 | 144.9 (89.8, 315.3) | 53 | 125.6 (86.2, 300.0) | 0.94† |
| Percentage change at week 48 | 153 | -47.7 (-79.7, -13.6) | 48 | 20.7 (-11.1, 113.0) | <0.001† |

IQR = interquartile ratio

\*p-value was from the ANOVA model including treatment as a fixed effect

†p-value was from the 2-sided Wilcoxon rank sum test to compare the 2 treatment groups.

## Table S4. Fasting Lipid Parameters

|  |  |  |  |
| --- | --- | --- | --- |
|  | E/C/F/TAF(n=159) | ATV+RTV and FTC/TDF(n=53) | P-value† |
| Lipid Parameter  | n | Median (IQR) | n | Median (IQR) |
| Total cholesterol (mg/dL) |
| Baseline | 159 | 171 (148, 203) | 53 | 180 (154, 201) | 0.55 |
| Change at week 48 | 153 | 27 (7, 46) | 48 | 5 (-7, 24) | <0.001 |
| Direct LDL (mg/dL) |
| Baseline | 159 | 105 (89, 133) | 53 | 115 (95, 133) | 0.43 |
| Change at week 48 | 153 | 16 (1, 34) | 48 | 8 (-10, 18) | 0.002 |
| HDL (mg/dL) |
| Baseline | 159 | 50 (43, 61) | 53 | 56 (44, 64) | 0.43 |
| Change at week 48 | 153 | 5 (-1, 12) | 48 | 0 (-4, 7) | 0.009 |
| Triglycerides (mg/dL) |
| Baseline | 159 | 105 (80, 141) | 53 | 105 (80, 136) | 0.60 |
| Change at week 48 | 153 | 3 (-20, 33) | 48 | 11 (-9, 41) | 0.30 |
| Total cholesterol to HDL ratio |
| Baseline | 159 | 3.3 (2.8, 4.1) | 53 | 3.2 (2.7, 4.1) | 0.72 |
| Change at week 48 | 153 | 0.1 (-0.1, 0.5) | 48 | 0.0 (-0.3, 0.4) | 0.075 |

IQR = interquartile ratio

†P-values were from the 2-sided Wilcoxon rank sum test to compare the 2 treatment groups

## Figure S1. Study profile



ATV=atazanavir; E/C/F/TAF= coformulated elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide; FTC/TDF=coformulated emtricitabine and tenofovir disoproxil fumarate; RTV=ritonavir

## Figure S2. Forest plot of treatment difference in virologic success at OLE week 48 (HIV-1 RNA <50 copies/mL, snapshot algorithm) by subgroup

