Background

- Co-formulated elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TDF) has been shown to be safe, efficacious, and well-tolerated in HIV-infected, treatment-naïve adults.

- Observational studies indicate that virologic and clinical outcomes are better for patients who receive co-formulated PI/NS3 inhibitors as first-line therapy.

- Strategies to achieve virologic suppression and to treat patient populations using a PI/NS3 inhibitor who may benefit from switching to a single-tablet regimen of E/C/F/TDF.

Method

- Multicenter, prospective, randomized, open-label, 24-week study.

- Eligibility criteria:
  - On boosted protease inhibitor regimen at least 6 months.
  - No history of virologic failure and no resistance to FTC or TDF on historical genotype.

- On first or second antiretroviral regimen.

- Change in CD4 cell count, safety, and tolerability of the PI + RTV + FTC/TDF.

- No subject discontinued study drug due to pancreatic, hepatic, or urinary disorders.

Results

- PI + RTV + FTC/TDF (n=139)

  - Efficacy and Differentiated Safety Compared to Atazanavir Boosted by Ritonavir Plus Emtricitabine/Tenofovir

- Comparison with baseline:
  - Changes from baseline at Week 48: median, Q1, Q3 (mg/dL)

- Safety:
  - Most adverse events were grade 1 or 2 in severity

- Efficacy:
  - Rates of virologic suppression

- Conclusion:
  - Switching to E/C/F/TDF from PI + RTV + FTC/TDF was evidenced in maintaining virologic suppression at Week 48.
  - E/C/F/TDF compared to PTV/FTV had significantly higher rates of virologic suppression.
  - E/C/F/TDF was well tolerated with low rates of discontinuation due to adverse events.

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