Methods

Statistical Approaches to Missing Data for the Metabolic Analyses

- Last Observation Carried Forward approach
- Complete case analysis

Analysis

- The primary outcome for longitudinal metabolic endpoints was the percent change from baseline, which was based on the measurements of the patients who were measured at baseline and the time point being analyzed.

Overall Efficacy and Safety Results

- No patients in the RAL treatment group reported clinical adverse events, whereas 6 patients in the EFV group reported 9 adverse events.
- Both adverse experiences were of mild intensity and neither were considered drug-related.
- There were no patients in the RAL treatment group that reported clinical adverse events.

Results

Mean Change from Baseline in Metabolic Parameters

- Percent of patients who achieved NCEP goals at endpoint:
  - Baseline: 10, 94.3% vs. 12, 91.9%
  - Week 48: 10, 94.3% vs. 12, 91.9%
  - Change (95% CI): 32.0% (18.0%, 46.0%) vs. 26.4% (12.4%, 40.4%)

Body Composition Changes through 48 Weeks

- Mean % change from baseline in fat mass and lean mass:
  - RAL: -6.0% (95% CI: -10.0%, -2.0%)
  - EFV: -1.5% (95% CI: -5.0%, 2.0%)

Baseline Characteristics

- Baseline characteristics of the patients in the RAL and EFV groups were similar.
- The mean age of the patients was 48 years, and the majority were male (72.9%).

Mean Change from Baseline

- The mean change from baseline in total cholesterol (T CHOL), LDL cholesterol (LDL-C), and triglycerides (TRIG) at week 48 were:
  - RAL: -18.0% (12.0%, 24.0%), -25.0% (19.0%, 31.0%), -30.0% (24.0%, 36.0%)
  - EFV: -12.0% (6.0%, 18.0%), -18.0% (12.0%, 24.0%), -20.0% (14.0%, 26.0%)

Conclusions

- RAL was generally better tolerated than EFV.
- RAL exerted a greater immunological effect than EFV, measured by the increase in CD4 cell counts.
- There were no patients in the RAL treatment group that reported clinical adverse events.