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two STRs FTC/RPV/TDF and EFV/FTC/TDF in ARV-naive adult patients ($N = 700$). The primary endpoint of the study is non-inferiority (12% margin) of FTC/RPV/TDF relative to EFV/FTC/TDF in achieving HIV-1 RNA <50 copies mL^{-1} at week 48. Secondary objectives of the study include evaluating the efficacy, safety and tolerability of the two regimens through 96 weeks, assessing the change from baseline in CD4 count in each treatment arm at weeks 48 and 96, assessing resistance at virologic failure and evaluating the change from baseline in fasting lipid parameters at weeks 48 and 96. Patient-reported outcome data will also be captured during the study. Primary endpoint results from STAR were anticipated in late 2012.[52]

Study 115 is an ongoing Phase 3b randomized, international, open-label, 96-week trial evaluating switching from a PI + RTV-based regimen to the EVG/COBI/FTC/TDF STR in virologically suppressed patients ($N = 420$). Patients will be randomized 2 : 1 to switch to the EVG/COBI/FTC/TDF STR at baseline or continue on their PI + RTV-based regimen for 96 weeks. The primary endpoint of the study is non-inferiority (12% margin) of switching to EVG/COBI/FTC/TDF relative to remaining on a PI + RTV-based regimen in maintaining HIV-1 RNA <50 copies mL^{-1} at week 48. Secondary objectives of the study include assessing the safety and tolerability of each treatment arm through 96 weeks and evaluating the change from baseline in CD4 cell count at weeks 48 and 96. Primary endpoint results are planned for 2013.[52]

Study 121 is an ongoing Phase 3b randomized, international, open-label, 96-week trial evaluating switching from an NNRTI-based regimen to the EVG/COBI/FTC/TDF STR in virologically suppressed patients ($N = 420$). Patients will be randomized 2 : 1 to switch to the EVG/COBI/FTC/TDF STR at baseline or continue on their NNRTI-based regimen for 96 weeks. The primary endpoint of the study is non-inferiority (12% margin) of switching to EVG/COBI/FTC/TDF relative to remaining on an NNRTI-based regimen in maintaining HIV-1 RNA <50 copies mL^{-1} at week 48. Secondary objectives of the study include assessing the safety, efficacy and tolerability of each treatment arm over 96 weeks and evaluating the change from baseline in lipid parameters at weeks 48 and 96. Patient-reported outcomes including adherence and quality of life outcomes will also be captured in the study. Primary endpoint results are anticipated in 2013.[52]

Study 123 is an ongoing Phase 3b single-arm, open-label, 48-week study evaluating virologically suppressed patients who switch from raltegravir (RAL) + FTC/TDF to the EVG/COBI/FTC/TDF STR ($N = 50$). The primary endpoint is to evaluate the proportion of patients with HIV-1 RNA <50 copies mL^{-1} at week 12. Secondary endpoints will include safety, efficacy and tolerability of EVG/COBI/FTC/TDF STR through 24 and 48 weeks after switching. Primary endpoint results are expected in 2013.[52]

14.9 Pipeline

Owing to the success of currently available STRs, several new STRs for the treatment of HIV are currently being pursued in clinical development to