provide patients with even more safe and effective treatment options with one pill once-daily dosing. The STRs in the pipeline generally contain novel coformulations of two or three previously-approved drugs combined with a new investigational ARV agent. The STRs in development include a tablet based on the newest member of the INSTI class, dolutegravir (DTG), and also the first PI-based STR. Other investigational agents currently in development such as non-catalytic site integrase inhibitors (NCINIs) may provide further opportunities for the formulation of future STRs. The expansion of STRs into almost all classes of commonly prescribed ARV agents opens up the potential for a simple and convenient treatment regimen to an even wider population of HIV-infected individuals.

SINGLE is an ongoing Phase 3 randomized, double-blind, double-dummy, 96-week, non-inferiority study comparing the DTG/ABC/3TC STR and the EFV/FTC/TDF STR in treatment-naive adults ($N = 800$). The primary endpoint of the study is the proportion of patients with HIV-1 RNA < 50 copies mL^{-1} at week 48. Secondary endpoint analyses will include safety, tolerability, immunologic activity, viral resistance and patient-reported outcomes. Primary endpoint results from this study were expected in late 2012 and will be used to support a future regulatory filing for DTG approval.[52]

Two of the newest STRs currently in clinical development, including the first PI-based STR, contain the investigational NNRTI GS-7340. GS-7340 is a novel amidate tenofovir prodrug that has the potential to improve upon the safety and efficacy of TDF by targeting delivery of high concentrations of tenofovir to lymphoid cells.[50,51] This increased specificity and potency allow for a lower dose of GS-7340 relative to TDF and may permit the development of new STRs not previously possible.

A Phase 2 study is currently under way evaluating the next-generation EVG/COBI/FTC/7340 STR compared with the EVG/COBI/FTC/TDF STR in ARV-naive adult patients ($N = 150$). This is a double-blind, placebo-controlled, 48-week safety and efficacy study where patients are randomized (2 : 1) to receive either EVG/COBI/FTC/7340 or EVG/COBI/FTC/TDF. The primary endpoint of the study is the proportion of patients with HIV-1 RNA < 50 copies mL^{-1} in each treatment arm at week 24. Secondary objectives include efficacy through week 48 and change from baseline in CD4 cell count from baseline at weeks 24 and 48. Primary endpoint results are expected in 2013.[52]

Another Phase 2 study is ongoing to evaluate the GS-7340-based PI-containing STR (DRV/COBI/FTC/7340) compared with the EVG/COBI/FTC/TDF STR in ARV-naive adult patients. This is a double-blind, placebo-controlled, 48-week safety and efficacy study where patients are randomized (2 : 1) to receive either DRV/COBI/FTC/7340 or EVG/COBI/FTC/TDF. The primary endpoint of the study is the proportion of patients with HIV-1 RNA < 50 copies mL^{-1} in each treatment arm at week 24. Secondary objectives include efficacy through week 48 and change from baseline in CD4 cell count from baseline at weeks 24 and 48. Primary endpoint results are expected in 2013.[52]