AA PILOT STUDY OF SAQUINAVIR-SGC (SQV) AND LOPINAVIR /RITONAVIR (LPV/R) TWICE DAILY IN PROTEASE INHIBITOR (PI) NAIVE HIV+ INDIVIDUALS: PROTEASE INHIBITOR CONCENTRATIONS AND WEEK 24 RESULTS.

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BACKGROUND: We designed a dual boosted regimen using saquinavir and lopinavir /ritonavir, without nucleosides in PI-naive subjects. OBJECTIVES: To evaluate the Ctrough, safety and antiviral activity of SQV 1000 mg plus LPV/r 400 mg/100 mg BID. METHODS: Prospective, open-label 48 week (w) study of safety and antiviral activity in PI-naive subjects with HIV RNA viral load (VL) >1000 copies/ml with tenofovir (TFV) intensification after w12 according to VL response. Trough LPV and SQV plasma concentrations determined by Virco, Belgium. RESULTS: n=20. Male 85%, African-American 40%, MSM 85%; Mean age 43 years. Mean VL log 4.4; CD4=274 cells/mm3. Baseline genotype confirmed the lack of PI resistance. GI intolerance in six (30%) required dose reduction, and two showed prompt resolution of intolerance with substitution of SQV HGC. Two subjects discontinued before w24 due to adverse events. Two subjects required TFV intensification. Intent to treat analysis (ITT) (Non-completer=failure) at w24: (17/20) 85%have VL <400 copies/ml and 65%<50 copies/ml. On treatment at w24: 94%(17/18) have VL <400 copies/ml, and 72%<50 copies/ml. CD4+ cell counts increased a mean 165 cells/mm3 at w24. W4 mean trough (n=15): [SQV]=1054 microg/ml (range 137-2070); [LPV]=5780 microg/ml (range 1844-9070). Complete w48 data including drug levels vs VL response, fasting lipids and lipodystrophy assessments will be presented. CONCLUSIONS: At week 24, the combination of SQV and LPV/r without nucleosides results in potent VL suppression and CD4 response, high levels of both SQV and LPV, with a good safety profile.

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