Phenotypic resistance testing significantly improves response to therapy: A randomized trial (VIRA3001).

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Design: An open-label, randomized, multicenter study designed to evaluate prospective phenotypic resistance testing by comparing the virologic and immunologic outcome of therapy (Tx) switches guided by phenotypic resistance testing (PRT) results vs. switches guided by standard of care (SOC) in subjects who have failed to achieve virologic suppression in their first PI-containing HAART regimen. 271 subjects with >/ =2 NRTIs and 1 PI prior Tx and plasma viral load (VL) >2,000 c/mL were randomized to Tx guided by PRT results using the Virco AntivirogramTM assay vs. SOC and followed for 16 weeks. Objective: Outcomes include percent of subjects >400 c/mL at Wk 16, VL change from baseline (BL), and CD4+ cell change from BL. Results: An interim analysis of subjects who started Tx at Day 1 (n =218) shows mean BL CD4+ cells counts of 339 and 345 cells/mm3 and VL of 4.2 log10 and 3.9 log10 for the PRT and SOC arms, respectively. NFV and IDV accounted for 53%and 36%of prior PI use, while 3TC (95%), ZDV (83%), d4T (61%), ddI (31%), and ddC (12%) accounted for prior accumulated NRTI use at study entry. An ITT observed analysis of subjects at Wk 16 showed that 58%and 37%of subjects in the PRT and SOC arms, respectively, had VL >400 c/mL of plasma (p =0.011). Similar trends in percent of subjects >400 c/mL of plasma at Wk 16 were observed when results were stratified by BL VL (>10,000, 10,000-100,000, and >100,000 c/mL of plasma). The median decrease in VL from BL at Wk 16 was -0.75 log10 and -1.27 log10 for the SOC and PRT arms, respectively (p > 0.02, ITT observed). CD4+ cell count increases were not significantly different between the arms. Conclusions: An interim analysis suggests that phenotypic resistance testing significantly improves virologic outcome when used by physicians to guide Tx choices for subjects who have failed to achieve virologic suppression using their first PI-containing regimen. The full data set and final analysis will be presented.

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