

Raltegravir Plus Optimized Background for Salvage in a Community Based Practice

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Abstract:

Background: The HIV-1 integrase inhibitor raltegravir (RAL), available in expanded access, provides new opportunities for salvage of highly experienced patients.

Methods: RAL + optimized background antiretrovirals (OBR) was administered by investigator choice to viremic triple class resistant patients.

Results: 20 subjects received RAL. The mean baseline viral load (VL) by bDNA was 97,535 copies and CD-4 count was 151. Previous protease inhibitor usage was 5.3 drugs. Mean GSS and PSS scores were 2.8 and 2.5 respectively, where those naïve to enfuvirtide (ENF) earned a score of 1. 17 were naïve to darunavir (DRV), while 13 received DRV in the OBR. 13 patients were naïve to ENF, however only 1 received ENF in OBR. 18/20 (90%) had VL <400 at 4 weeks; 12/20 (60%) had VL <75 and 11 of those 12 were DRV naïve at baseline. At 10 weeks, 15/17 (88%) had VL <400 and 13/17 (77%) had VL <75. The log₁₀ change in VL overall at 4 weeks was -2.4. There was no significant decline in VL after 4 weeks. CD4 counts increased by 81 cells in the first 4 weeks overall, and by an additional 29 cells (110 cells total) at 10 weeks for 16/20 evaluable patients. Multivariate regression analysis examining the change in VL and CD-4 from baseline, controlling for ARV regimen prior to RAL as well as OBR was performed. We did not find significant correlates for the observed VL reduction in the OBR, including DRV and ENF. Patients with higher baseline VLs had a larger increase in CD4 at 4 weeks. All results significant at 95% level. RAL was well tolerated.

Conclusions: RAL was a potent foundation for salvage regimens in triple class resistant patients. It produced rapid declines in VL and more gradual recovery of CD4 cell counts. Outcome at 10 weeks was independent of DRV and ENF in OBR. Effects on VL suppression to <400 and <75 and on CD-4 count confirmed those reported in Benchmark studies.

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