

National AIDS Treatment Advocacy Project

Ritonavir, ddC and AZT: Abbott French Study #208 of Triple Therapy, presented at Vancouver Abbott Symposium July 10, 1996

At the Human Retrovirus Conference in January of 1996, 6 months data from this study were publicly presented for the first time. Presented in Vancouver was an extension of the data out to 60 weeks.

The drug regimen used was AZT (200 mg, tid or 3X/day), ddC (0.75 mg, tid) and ritonavir (600 mg, bid). Initially in this study, the distasteful oral solution of ritonavir was being given to study subjects. At 52 weeks, the capsules were made available and apparently compliance was better. Open-label ritonavir (600 mg, bid) monotherapy was administered for 14 days followed immediately by the addition of AZT and ddC.

Thirty-two study subjects with no previous antiretroviral therapy were enrolled with CD4 between 50-250 cells/mm³, or a drop of 200 cells/mm³ to a level of less than 350 cells/mm³ over a recent 6 month period, or 250 to 350 cells/mm³ with symptoms. Monitoring for efficacy and safety included HIV RNA plasma viral load (quantitative RT-PCR test from Roche), CD4 and CD8 lymphocytes counts and standard laboratory tests.

The baseline measures: median CD4 cell count was 180

- median HIV RNA in plasma was 4.8 log--63,000 copies (range 3.05-5.39; 1,122 - 245,471) and median cellular viremia was 3.5 x 10 million (range 0.78-4.30 x 10 million)
- mean reduction in HIV RNA plasma viral load:
week 8 : 2.0 log (n=27)
week 24: 2.0 log (n=21)
week 60: 1.9 log (n=17)

The percentage of subjects with undetectable (below 200 copies) HIV RNA in plasma were 47% at 28 weeks, 60% at 36 weeks, 50% at 54 weeks and 60% (n=15) at 60 weeks.

- mean reduction in cellular viremia (infectious cells):
week 8 : 2.1 log (n=26)
week 24: 2.4 log (n=21)
week 60: 2.4 log (n=17)

The percentage of subjects who had cellular viremia below the level of detection (5 infectious cells per 10⁷ PBMC) was 30% at 24 weeks and 60% at 60 weeks.

- mean CD4 count was 170 cells at baseline:
week 8 : 280 (n=26)
week 24: 304 (n=21)
week 60: 338 (n=17)

Eleven subjects discontinued therapy during the first six months, and six of these were contributed to the ritonavir oral solution; 2 discontinuations were due to hepatic toxicity of ritonavir. Abbott said that, following the introduction of capsules in place of the oral solution, compliance with ritonavir appears to be improved.