

Interrupting Antiretroviral Therapy (ART) using CD4+ T-cell counts  $< 350/\text{mm}^3$  to restart ART (ACTG A5102).

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**Background:** Indication for continuous ART, among patients with HIV RNA  $< 200$  copies/ml and CD4 cell count  $> 500/\text{mm}^3$  are not known. Strategies with IL-2 to boost CD4+ T cells, and pulses of ART could reduce cost and toxicity.

**Objective:** To evaluate 3 cycles of IL-2 prior to treatment interruption (TI) on the time off ART, utilizing a CD4+ T-cell count  $< 350/\text{mm}^3$  as the threshold.

**Design:** 47 HIV+ subjects on their first potent ART with CD4+ T-cells  $> 500/\text{mm}^3$  and HIV RNA  $< 200$  copies/ml were randomized to Arm A (ART + IL-2 @ 4.5 million units sc BID for 5 days every 8 weeks x 3, n=23) or Arm B (ART only, n=24) for 18 weeks.

**Results:** Median (M) baseline CD4 were  $810 \text{ cells}/\text{mm}^3$  with 96% HIV-RNA number  $< 50$  copies/ml. Pre-ART M CD4 nadir was  $344 \text{ cells}/\text{mm}^3$  and M HIV RNA s  $4.41 \log_{10}$  copies/ml. M CD4 at TI was  $1331 \text{ cells}/\text{mm}^3$  (Arm A) and  $757 \text{ cells}/\text{mm}^3$  (Arm B). Ten subjects have reinitiated ART and 5 subjects are off study as of Jan. 2004. M CD4 at week 48 after TI was  $671 \text{ cells}/\text{mm}^3$  (A) and  $480 \text{ cells}/\text{mm}^3$  for (B). The M time to virologic set point was 16 weeks for both groups. M HIV RNA was  $4.2 \log_{10}$  copies/ml at week 8 and  $4.3 \log_{10}$  copies/ml at week 48. Time to restarting ART was longer in the IL-2 arm vs no IL-2 arm. Associations between the time to restarting ART and the CD4 count at TI, pre-ART nadir CD4 count, and the maximum HIV RNA rebound @ wk 8-24 and other factors will be presented.

**Conclusions:** Cycles of IL-2 increased CD4 cells prior to TI, providing a longer time to a CD4 count  $< 350 / \text{mm}^3$ . More than 50% of subjects remain off ART at one year, without clinical events. Median HIV RNA on TI did not change over 16 to 48 weeks. These preliminary data suggest that TI can be safely maintained among  $> 50\%$  of subjects for more than 54 weeks, sparing costs and toxicities of ART among patients with suppressed HIV RNA levels and CD4 counts  $> 500 / \text{mm}^3$ .