

Poster presentation

## **PI8-14 LB. Vacc-4x HIV p24-like peptide vaccine-associated increase of CD4 T-cells in chronically infected HIV-1 patients on antiretroviral therapy**

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### **Background**

Since its implementation more than a decade ago combination Antiretroviral Therapy (ART) has had a dramatic effect on HIV-1 induced mortality and morbidity. However, 15-20% of the patients initiating ART do not regain CD4 T-cells despite an effective suppression of HIV-1 mRNA levels in blood. The incomplete therapeutic effect leaves these patients at elevated risk of disease complications and death. Attempts to reduce clinical events through IL-2 induced stimulation of CD4 T-cells in the ESPRIT and SILCAAT studies have not proven to be successful. Until further research has given better opportunities for a successful direct induction of functional CD4 cells a logical alternative may be to increase CD4 counts indirectly by improving anti-HIV effect while on ART using antigen-specific immune stimulation with an effective HIV-vaccine.

### **Methods**

In a Phase II trial with Vacc-4x, a synthetic and specific peptide vaccine to HIV-1 p24Gag, the increase of CD4 cells was studied in 37 chronically infected HIV patients on ART and with varying baseline CD4 T-cell counts. The median duration of ART prior to Vacc-4x immunization was 4.5 years and preART CD4 counts were median 295 cells/uL.

### **Results**

The average increase of CD4 counts was 9% ( $P < 0,05$ ) above baseline at 585 cell/uL (mean) 6 weeks after immu-

nization. For patients with baseline CD4 level  $<500$  cells/uL ( $n = 11$ ) the increase was 25% ( $P < 0,05$ ) or 105 cells/uL. Only a few patients had a baseline CD4 count  $<400$  ( $n = 3$ ) with an average increase of 32% (NS).

### **Conclusion**

Patients on ART immunized with Vacc-4x experienced increased CD4 counts. The effect appeared more pronounced in patients with lower baseline CD4 counts ( $<400-500$ ). In a previous study (ACTG 384) CD4 increase for patients (preART CD4 $<300$ ) was minimal after 120 weeks on ART (RobbinsCID 2009,48, 350-61).