Enhancing HIV-1 specific immunity without compromising CD4+ T cell activation may clearly productively infected cells, a key aspect of eradication strategies. AGS-004 consists of matured autologous dendritic cells (DCs) co-electroporated in vitro with chemically synthesized HIV-1 RNA to achieve DC functionality.

**METHODS**

- **Open-label**, single arm sub-study of AGS-004-003
- 6 male patients who initiated ART within 45 days of acute HIV infection (HIV RNA <50 c/ml for >6 months). AHI defined as negative/indeterminate EIA or negative HIV RNA test within 45 days of detectable plasma HIV RNA.
- Monthly doses of AGS-004 administered on ART; immune responses (IR) assessed after 3-4 doses (wk 13-16).
- Positive IR defined as a ≥2-fold increase from baseline in the number of CD8+/CD45RA- CTL measured by quantitative viral outgrowth assay (VQA) or CD28-surface markers.
- ART restarted if CD4 count <350 cell/mm3; >20% decline in absolute CD4 count or percentage, or confirmed HIV RNA >10,000 c/ml.
- HIV RNA was measured by a single-copy assay (SCA).
- Frequency of resting CD4+ T-cell infection (RCI) was measured by quantitative viral outgrowth assay (VQA) at baseline and after 3 doses (wk 10).

**RESULTS**

- Few treatment-related AEs were all Grade 1.
- All participants met criteria for positive IR and ATI.
- Median ATI duration was 58 days (range 36-147).
- One participant remains in ATI after 268 days.
- Baseline SCA was <1 c/ml in all participants.
- Only 1 participant (54-100) had a ≥2-fold decrease in frequency of RCI at W10 but maintained ATI for 90d.

**CONCLUSIONS**

- **AGS-004 DC therapy was safe, well-tolerated, and led to increased HIV-specific immune responses, but did not allow sustained ART interruption.**
- The one participant with a ≥2-fold decrease in the frequency of ATI at week 10 underwent ATI for 90 days.
- However, this DC therapy might result in depletion of persistent HIV infection in ART-suppressed patients following administration of anti-latency therapy.
- Next step: determine the optimal timing of administration of an anti-latency compound following 4 doses of AGS-004.