BACKGROUND

- Our prior study NCT00554860 demonstrated that a 20-week course of IFN-α2b pegylation was well-tolerated and resulted in a significant reduction in peripheral proviral DNA. Pegylated interferon-α2b (PEG-IFN-α2b) is a major factor of a high level of antibodies against IFN-α.

- Recent HIV infection studies suggest that a specific viral load (HIV viral load) is a predictor of resistance to IFN therapy. Pegylated interferon-α2b combined with potent antiretroviral therapy (ART) may be a promising treatment for HIV infection.

- Prior diagnosis of multiple sclerosis or other neurodegenerative disorders (NDPs) is a significant predictor of resistance to IFN therapy. Pegylated interferon-α2b combined with potent antiretroviral therapy (ART) may be a promising treatment for HIV infection.

OBJECTIVES

- The long-term goal of this research is to evaluate the efficacy of peg-IFN-α2b as an anti-HIV therapy to potentiate eradication strategies against HIV. The short-term goals of this proposal are to determine whether peg-IFN-α2b can reduce viral DNA levels in circulating proviral DNA and (as detected by a proviral polymerase chain reaction) in HIV-infected individuals who achieve licensing to antiretroviral therapy (ART) and have a low viral load.

- To determine whether peg-IFN-α2b therapy reduces HIV viral load in patients with no previous antiretroviral therapy (ART) experience.

- To evaluate the safety and efficacy of peg-IFN-α2b combined with potent antiretroviral therapy (ART) in the treatment of HIV-infected individuals.

RESULTS

- Demographics:
  - Gender: Male (50%), Female (50%)
  - Age: 18-65 years of age

- Baseline characteristics:
  - CD4+ T-cell count (copy/mL): 200-500
  - HIV viral load (copy/mL): <50
  - ALT (U/L): 0-1UL

- Study population:
  - Clinical sites: Pennsylvania, New York, and Georgia

SAFETY DATA

- Data collected: Clinical labs (CBC w/ differential), LFTS, KFTS, ELECTROLYTES

LIPIDS, LFTS, KFTS, ELECTROLYTES

- Samples collected: Baseline, Week 1, Week 2

- Study scheme:
  - Visit 1 (pre-treatment): Week 0
  - Visit 2 (week 2): Week 1

UPCOMING STUDIES

- Pilot study to evaluate the efficacy of peg-IFN-α2b as an anti-HIV therapy to potentiate eradication strategies against HIV.

- Clinical study to evaluate the safety and efficacy of peg-IFN-α2b combined with potent antiretroviral therapy (ART) in the treatment of HIV-infected individuals.

CONCLUSIONS AND FUTURE DIRECTIONS

- The results of this study will provide valuable insights into the efficacy and safety of peg-IFN-α2b in the treatment of HIV infection.

- Future studies will focus on evaluating the long-term effects of peg-IFN-α2b on HIV-infected patients and their adherence to ART.

- The data collected will be used to inform future research and clinical practice in HIV infection.