Researchers present Phase II HIV gene therapy trial data at CROI 2010

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Researchers from the University of Pennsylvania School of Medicine presented today the results from an ongoing Phase I/II open-label clinical trial of Lexgenleucel-T at the 16th Conference on Retroviruses and Opportunistic Infections (CROI) in San Francisco, CA.

Lexgenleucel-T is a cell and gene therapy product being investigated for the treatment of HIV infection. The current study examined the effect of Lexgenleucel-T infusions in HIV-1 infected individuals prior to being taken off their antiretroviral treatment (HAART) regimens as part of the study design's scheduled treatment interruption. In the study, seven of eight evaluable subjects experienced a decrease in viral load set point and one subject experienced prolonged, complete control of HIV viremia for more than 14 weeks in the absence of HAART. Viral load set point is the HIV RNA value specific for each infected individual in absence of anti-retroviral drug control. Higher viral load set point is correlated with more rapid disease progression to AIDS.

"We are excited to see these responses using autologous transfer of CD4+ T lymphocytes genetically modified with VRX496TM, a HIV-

based lentiviral vector encoding for a RNA antisense targeting HIV env. These are subjects who were taken off of their antiretroviral treatment and are showing a better control of their infection as demonstrated by reduced viral load set points," said Pablo Tebas, M.D., director of the Adult AIDS Clinical Trials Unit, who presented the results at CROI. "Further study is needed to see whether these types of results will translate into a delay in disease progression."

In the current study, several administrations of Lexgenleucel-T, each comprising approximately 1010 autologous CD4+ T cells transduced ex vivo with VRX496TM, were administered to 17 HIV-1 infected subjects who were fully suppressed on HAART. Each subject received three to six separate infusions over a period up to 13 weeks. Six weeks after the last infusion, eligible subjects underwent a scheduled treatment interruption to evaluate timing to HIV RNA recrudescence, changes in viral load set point and changes in CD4 T cell count. Of the 17 subjects who received infusions, 13 (76%) underwent the scheduled treatment interruption. Eight of these 13 subjects (62%) were evaluable for the efficacy endpoint. Overall, 7 of 8 (88%) of the evaluable subjects had a decrease in viral load set point ranging from -0.26 to -0.98 Log10. One subject maintained a complete control of HIV RNA viral load below the limit of detection (50 copies/ml) and a CD4+ cell count greater than 1200 cells/μL for over 14 weeks.

"It is notable that all patients on the protocol had elevated CD4+ counts after treatment with Lexgenleucel-T," said Carl June, M.D., professor of Pathology and Laboratory Medicine. "Achieving a complete control of HIV recrudescence following HAART interruption for over 14 weeks is, indeed, remarkable."

Provided by University of Pennsylvania School of Medicine