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NOVEL HIV GENE THERAPY YIELDS EXCITING RESULTS IN PHASE I CLINICAL TRIAL

GAITHERSBURG, MD – Monday, February 28, 2005 - VIRxSYS Corporation, a private biotechnology company focused on the development of gene therapy treatments for diseases such as HIV/AIDS and cancer, reports unexpected and unprecedented findings in its ongoing Phase I clinical trial of its VRX496 therapy in patients with HIV. The findings were presented last week in Boston at the Conference of Retroviruses and Opportunistic Infections (CROI) by the clinical trial's co-principal investigator, Dr. Carl June of the University of Pennsylvania.

The principal purpose of the Phase I clinical trial is to establish the safety of the VRX496 therapy in patients failing two or more HAART regimens. Each of the five patients in the clinical trial has been dosed with a single infusion of VRX496, and none has experienced any serious adverse events related to the treatment. In addition to this demonstration of safety, each of the three patients who has completed his/her one-year post-dosing assessment unexpectedly showed a clinically significant decrease in viral load, which is a measure of HIV's presence in the body. The fourth and fifth patients have completed their six- and three-month assessments, respectively, and their viral loads remain stable. The one-year post-dosing assessments of these two patients will be completed in July and September of this year.

In addition to these viral load findings, the CD4 T cells, typically destroyed by HIV, remain stable in the first patient and increased by 20% and 35% in the second and third patients, respectively. The fourth and fifth patients' CD4 T cell counts also remain stable.

"We believe the VIRxSYS' VRX496 therapy has the potential to become the next generation of HIV treatment. The patients in our clinical trial have multiple-drug resistant HIV, but nevertheless are responding well to this gene therapy," says Riku Rautsola, Ph.D., CEO-designate of VIRxSYS. "We congratulate Dr. June for his groundbreaking work on this clinical trial."

In addition to the favorable impact on patient viral load and CD4 T cell counts, data from the clinical trial suggest that the VRX496 is restoring a healthy immune system in these HIV patients. Three of the five patients in the trial developed an improved immune

response to HIV and also to diphtheria toxin. “These results suggest that immune reconstitution occurred in the patients on the protocol, and that immunity may be enhanced for HIV and other infectious pathogens,” says Dr. June.

The VRX496 used in the Phase I clinical trial is an HIV-derived lentiviral vector from which the disease-causing aspects of the virus have been removed, leaving behind an efficient genetic delivery vehicle. This vector is then equipped with an anti-HIV genetic medicine consisting of a long antisense molecule targeted against the HIV envelope gene. This antisense genetic medicine blocks HIV replication in CD4 T cells, which would otherwise be destroyed by the HIV virus. Without CD4 T cells, the immune system would collapse, allowing the onset of full-blown AIDS.

The VIRxSYS therapy modifies a patient’s CD4 T cells with its lentiviral vector to provide the patient with a critical mass of protected CD4 T cells capable of resisting HIV so they can continue their normal immune function. The effect of this therapy is to repopulate a patient’s immune system with cells that can support immunity against HIV and other infections.

Gene therapy clinical trials have faced many hurdles in the past, most significantly with identifying an efficient vector to deliver an effective and permanent therapeutic payload. “An important aspect to our therapy is that the high efficiency of lentiviral vector gene transfer, combined with the delivery of a genetic payload, instead of protein payload, overcomes two major obstacles that have hindered success in past gene therapy clinical trials,” states Dr. Rautsola.

Based on these promising results from the Phase I clinical trial, VIRxSYS plans to meet with the U.S. Food and Drug Administration in early March 2005 to present Phase I results and discuss plans for a controlled, multi-center, multi-dose trial. Based on a favorable outcome from this meeting, VIRxSYS would commence a Phase II study in the 2nd Quarter of 2005. A separate Phase I/II clinical trial examining the potential role of VRX496 in extending HIV patients’ drug holidays will be started simultaneously at the University of Pennsylvania by Dr. June and his colleagues.

About the Company

VIRxSYS is a private biotechnology company founded in 1998, which focuses on the development of a novel HIV lentiviral vector platform technology for the treatment of serious diseases such as HIV/AIDS and cancer. The Company’s highly patented, proprietary technology platform and product application strategy is based on research originally conducted at and exclusively licensed from The Johns Hopkins University (JHU) in Baltimore, Maryland. Additional information is available at VIRxSYS’ website at www.virxsys.com.

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