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VIRxSYS Corporation Announces Publication of Phase I Study of Novel Gene Therapy for HIV

First Clinical Evaluation of a Lentiviral Vector Promising for Patients with HIV

GAITHERSBURG, MD – November 6, 2006 –VIRxSYS Corporation announced today the publication of results from their Phase I, open-label, non-randomized clinical trial evaluating VRX496, a gene-based immunotherapy for the treatment of HIV. Results of the Phase I trial conducted at the University of Pennsylvania School of Medicine were published today in the *Proceedings of the National Academy of Sciences*. The trial evaluated the safety and tolerability of VRX496, enrolling five subjects with chronic HIV infection who had failed to respond to at least two antiretroviral (ARV) drug regimens. Each of the five patients who tolerated the gene therapy treatment experienced decreases in viral load and experienced stable or increased CD4 T cell counts.

“Gene therapy has long been discussed as an alternative treatment to HIV,” says senior author Carl June, MD, from Penn. “The results from this Phase I trial are encouraging—particularly since these are late-stage patients—and demonstrate that gene therapy has the potential to treat HIV and other serious human diseases.”

VRX496, a CD4 T cell treatment against HIV, is the first application of VIRxSYS’ lentiviral vector platform. It is the first, and continues to be the only, lentiviral vector currently administered in human clinical trials approved by the U.S. Food and Drug Administration. The backbone of VRX496 is an HIV-based lentiviral vector from which the disease-causing aspects of the virus have been removed, leaving behind an efficient gene-delivery vehicle. VIRxSYS then equips the vector with a long antisense sequence against the HIV envelope protein to create VRX496. Preclinical studies indicated that HIV is unable to mutate around VRX496’s antisense therapy, thus the HIV is unable to form resistant strains in treated patients. VRX496 is transduced into a patient’s own CD4 T cells to block HIV replication. Researchers believe this potentiates the immune response against HIV and restores normal immune function against other infections.

The Phase I trial demonstrated that a single intravenous infusion of autologous CD4 T cells genetically modified with VRX496 was safe and well tolerated. In addition to being monitored for adverse events over the course of the nine-month trial, subjects were also monitored for viral load, CD4 counts, immune response, and persistence of modified T cells. All patients had stable or decreased viral load, with three of the five patients exhibiting clinically significant reductions in viral load without changes in their ARV treatment at six months post infusion. Four of the five patients had stable or increased CD4 T cell counts. In addition, all five patients had stable or increased immune response to HIV antigens and other pathogens. Patients will have follow-up safety visits every

year for 15 years. Some patients that have reached the three year post-infusion safety visit continue to exhibit persistence of modified cells, decreased viral load and increased CD4 counts over baseline.

“This is an important milestone in the development of what we believe will be the next-generation of HIV therapy,” said Riku Rautsola, PhD, President and CEO of VIRxSYS. “VRX496 is engineered in a way that debilitates HIV’s ability to replicate and mutate around the therapy, overcoming a common problem with current drug treatments. The treatment of diseases like cancer and HIV infection has been a distant promise, but the success of our team and other groups has shown that we are moving toward practical therapies. The results of this trial also contribute to the growing opinion that lentiviral vectors are the most promising viral vectors for clinical applications”

Two Phase II trials testing the safety and tolerability of single and repeated doses of VRX496 are underway. Preliminary results from these trials should be available in 2007. In preclinical and clinical studies, VRX496 has been able to deliver genes permanently, reproducibly and efficiently to human cells without toxicity or serious adverse events, such as immunogenicity or insertional oncogenesis (cancer), that plagued earlier gene therapy trials.

About VIRxSYS

Founded in 1998, VIRxSYS is a private biotechnology company that develops therapies for serious diseases, such as HIV, cancer and genetic diseases, utilizing its novel lentiviral vector platform. The Company has exclusively licensed foundational technology from The Johns Hopkins University in Baltimore, Maryland, where the original research was conducted. The Company has developed additional patented technology relating to the application and manufacture of the lentiviral vector platform. More information regarding VIRxSYS can be found at www.virxsys.com. Details on the ongoing Phase II clinical trials may be found at the NIH clinical trials website at clinicaltrials.gov/show/NCT00131560.

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