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## **VIRxSYS' DSMB Recommends Continuation of Its Phase I Clinical Trial**

*The Clinical Trial is First-ever to Use Lentiviral Vectors for Gene Therapy in Humans*

Gaithersburg, MD – December 18, 2003 – VIRxSYS Corporation, a private biotechnology company focused on the development of genetic medicines for the treatment of serious diseases such as HIV/AIDS, announced today that a third patient will be treated in its Phase I trial with VRX496 modified T cells. An independent Data Safety Monitoring Board (DSMB) has reviewed initial safety data for its first two patients and unanimously recommended that the trial continue without any modifications. The clinical trial is the first-ever to use a promising new class of genetic vectors - lentiviral vectors - in humans.

Lentiviral vectors have been shown to deliver genetic payloads stably into primary human cells with high efficiency, a necessary prerequisite for effective genetic therapy. The ongoing trial involves the use of a HIV-based lentiviral vector as a potential treatment for HIV/AIDS.

"Initial safety data is very promising for the first two patients considering both had failed two HAART regimens and had limited drug treatment options left. The first two patients will continue to be monitored to ensure the safety of VRX496," stated Boro Dropulic, Ph.D., Founder and Chief Scientific Officer.

The trial is being led by University of Pennsylvania's Drs. Rob Roy MacGregor, principal investigator, and Carl H. June, co-investigator, both leaders in the fields of infectious diseases and T cell transplantation.

## **About the VRX496 Phase I trial**

The VRX496 Phase I trial involves the use of a HIV-based lentiviral vector where a muted or “guttled” form of the virus is genetically engineered to inhibit HIV replication and spread. T cells from HIV-infected patients are removed and treated with the HIV lentiviral vector and then are reintroduced into the patient. The goal for this new potential therapy for HIV/AIDS is to place the disease into permanent remission by creating an “army” of VRX496-containing CD4 T cells in the patient’s body that permanently suppresses HIV infection and reconstitutes the immune system to prevent the onset of symptomatic AIDS.

The trial plans to enroll a total of five patients who are infected with HIV and who have failed two-regimens of triple anti-retroviral drug therapy (HAART). Each patient will be enrolled after preceding patients show initial safety, as determined by the DSMB. The Phase I trial will be complete after sufficient safety data is accumulated on all 5 patients.

## **About VIRxSYS**

VIRxSYS Corporation 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 by VIRxSYS’ Founder and Chief Scientific Officer, Dr. Boro Dropulic. Signature Capital, the Company’s lead investor, is a unique venture capital company co-founded by Bill Sick and Bill Turner that specializes in identifying companies with innovative approaches. Additional information is available at VIRxSYS’ Web site at <http://www.virxsys.com>, and at Signature Capital’s Web site at <http://www.sigcap.com>.