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## **VIRxSYS TO INITIATE PHASE I CLINICAL TRIALS FOR INNOVATIVE TREATMENT OF HIV/AIDS**

**– New Experimental AIDS treatment aims to thwart development of disease in infected individuals by turning HIV against itself –**

Gaithersburg, MD – February 14, 2003 – VIRxSYS Corporation, a private biotechnology company focused on the development of novel genetic medicines and vaccines for the treatment and management of serious diseases such as HIV/AIDS and cancer, announced today that it will initiate Phase I clinical trials for the genetic treatment of HIV/AIDS. The trials will involve the first-ever use of a lentiviral vector in humans, called VRX496, whereby HIV is genetically turned against itself in a clinical setting. The therapeutic goal is to show in human trials what has been demonstrated in the laboratory and in small animals. In the laboratory, the VIRxSYS vector repeatedly showed extremely high delivery efficiency to CD4 T cells (immune cells), significant inhibition of HIV replication and ability to thwart wild-type HIV's (wt-HIV) tendency to create resistance to the treatment via mutation. In small animals, safety and non-toxicity of the VIRxSYS vector were also demonstrated.

The Phase I clinical trials are expected to begin in the next 90 days at the University of Pennsylvania's School of Medicine and will involve HIV infected patients, who have failed two consecutive combination anti-retroviral drug therapy regimens. The treatment involves the removal of T cells from patients infected with HIV, treating these immune cells with the HIV lentiviral vector and then reintroducing them back into the patient. The trials are 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 T cell transplantation and infectious diseases.

Dr. Boro Dropulic, Founder and Chief Scientific Officer of VIRxSYS, commented, “VIRxSYS has met the extensive requirements of the Recombinant Advisory Committee of the NIH, the Biological Response Modifier Committee of the FDA, and the FDA regarding appropriate pre-clinical safety testing of its VRX496 vector. Receiving clearance to initiate Phase I clinical trials for this new and promising class of vectors is as important a milestone for the company as it is for the field. Lentiviral vectors hold significant promise for the treatment of many disease states because they efficiently deliver payload genes into targeted human cells. The goal for HIV/AIDS is to permanently decrease viral loads to levels that are not conducive to disease and protect CD4 T cells from being killed by HIV so that they can fight and control the infection. We are optimistic that our approach will significantly improve the quality of life for individuals suffering from HIV/AIDS.”

VIRxSYS’ HIV lentiviral vector technology is a radically different approach to HIV treatment. Instead of developing newer classes of HIV replication blockers, VIRxSYS has developed a gutted version of HIV, called VRX496, by taking out the components that foster its replication and cause disease and inserting instead an anti-HIV ‘antisense’ payload that destroys the genetic material of HIV. This vector is then added to the CD4 T cells of an HIV-infected patient to enable that patient’s T cells to inhibit HIV replication and resist their destruction by HIV. VRX496 resides in these CD4 T cells in a dormant state until the infectious wt-HIV invades the cell. Upon infection and then subsequent activation of that cell, wt-HIV attempts to reproduce itself. This in turn triggers VRX496 replication that ultimately destroys the wt-HIV genetic material and prevents its replication.

The goal of the VIRxSYS treatment approach is to reverse and potentially cure individuals with HIV/AIDS by creating an “army” of VRX496-enabled CD4 T cells in the patient’s body that permanently suppresses HIV infection and restores the body’s immune system.

In pre-clinical trials, VIRxSYS consistently achieved greater than 90% T cell delivery with VRX496 and also repeatedly demonstrated a greater than 99% reduction in HIV viral replication in human immune cells. The introduction of sufficient numbers of the VRX496 enabled CD4 T cells into HIV infected individuals may permanently postpone AIDS disease progression and restore the patient's immune system.

Combination anti-retroviral drug therapy, currently commonly used for the treatment of HIV infected patients, is not a cure; rather, this treatment suppresses HIV replication as long as the patient adheres to the drug dosing requirements. Dr. Dropulic further explained, "Many patients have been forced to discontinue combination anti-retroviral drug therapy because strict and continual adherence to these drug regimens, essential for control of HIV replication, produces toxic side effects. In other patients, HIV has become resistant to these drugs, rendering them useless. VIRxSYS' lentiviral vectors have shown no toxic side effects in pre-clinical animal studies. Also, preclinical studies have shown that HIV cannot mutate around the long anti-HIV antisense payload contained within VRX496 and yet be sufficiently fit to replicate at levels that would be necessary to cause disease."

"VIRxSYS has made significant progress in this important new field of medicine," commented, Bob Ackmann, Interim Chief Executive Officer and Chief Financial Officer of VIRxSYS. "The Company believes that successful Phase I human clinical trials for this vector class will lead to new therapies for AIDS as well as an extension of the VIRxSYS technology platform to potentially create a vaccine for the disease."

### **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. VIRxSYS has taken proof-of-concept studies performed at JHU to Phase I clinical trials in just under four years. Signature Capital, the Company's lead investor, is a unique venture capital company co-founded and co-managed 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>.

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