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Vaccine Uses Modified HIV Lentivirus Vector; HIV Virus “Very Low to Undetectable” in Reservoirs
Functional Cure in Non-Human Primates Achieved With
Simian Version of VIRxSYS’ HIV Vaccine VRX1273

(Rome, Italy – July 17, 2011) Researchers from VIRxSYS Corporation, the Gaithersburg, Maryland-based biotechnology company, today presented data indicating that a simian version of its HIV vaccine VRX1273 achieved a functional cure in a subset of rhesus macaques that had been challenged with a high dose of simian immunodeficiency virus (SIV). At 18 months after the SIVmac251 infection, VIRxSYS researchers report that some of the vaccinated animals displayed viral loads below levels of detection in blood plasma, blood cells, and cells residing in tissues defined as “reservoirs.”

The data were presented at the 6th International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention. The abstract MOLBPE042, is authored by Franck Lemiale, PhD, Pharm. D., VIRxSYS’ Senior Director of Vaccine and Immunology.

“Developing a functional cure for HIV has become a major goal of the scientific community,” said Lawrence Michaelis, MD, President, CEO and Chairman of the Board of Directors at VIRxSYS. “We believe we have the potential to achieve it with our vaccine VRX1273, by reducing viral load significantly without concomitant antiretroviral drugs, preserving their immune compartment, and extending symptom-free survival, as seen in a subset of our highly infected, vaccinated monkeys. This is a significant milestone toward an immune-based functional cure for HIV.”

“Although this pre-clinical study is modest in terms of size, it is highly unusual to see near non-detectable levels of the virus not only circulating in the blood, but also in the reservoirs where HIV is known to replicate,” said Joep Lange, MD, PhD, Professor of Medicine at the Academic Medical Center, University of Amsterdam and Head of the Amsterdam Institute for Global Health and Development. “I know of no study, in humans or animals, which was able to reduce the frequency of virus infected cells in reservoirs to this extent.”

– M O R E –

On VRX1273 Study Design and Results

VIRxSYS researchers created a Simian version of its HIV vaccine VRX1273 and performed three subcutaneous injections over a period of six months in five animals. An additional five rhesus macaques were used as control group, which received a placebo vaccine. One animal had a genetic predisposition for controlling SIV when infected. This animal, which could be defined as an “elite controller” as an analogy to a similar sub-groups of naturally resistant humans, was included in the control group to serve as a benchmark for control of SIV replication.

The vaccine was well tolerated in all of the animals following each of the three injections, with no sign of toxicity, and it generated strong immune responses against the SIV antigens encoded by the vaccine, a key objective of the study.

Following the immunogenicity study, the researchers infected both vaccinated and unvaccinated animals with a high dose of SIVmac251, a highly infectious strain of SIV. All animals were closely monitored over an 18 month period after infecting them with this SIV. Clear indications of efficacy were demonstrated as some vaccinated animals showed a dramatic control of SIV replication, even superior to the SIV-replication control achieved by the “genetically gifted” Elite Controller in the control group. Notably, the vaccine effect was fully sustained in the responders still at the end of the 18 month monitoring period, a full two years after the last vaccination, without the use of any booster immunization.

Benefits of a Therapeutic Vaccine

Therapeutic vaccines are used to treat people already infected, such as the vaccine used for rabies. Unlike most of the other research conducted to fight HIV, therapeutic vaccines have the potential to create a “functional cure,” or a way to keep the virus in check so that it won’t overpower the immune system and endanger the patient. A successful therapeutic vaccine may also stop the forward transmission of the virus, creating a new weapon to prevent the spread of the disease. A successful therapeutic vaccine would offer significant benefits:

- Reduced risk of drug toxicities for people living with HIV
- Preservation of immune system function and stimulation of HIV-specific immunity
- Dramatically lower costs than current HAART drugs
- Reduced or eliminated HIV in reservoirs and sanctuary regions
- Easier administration and less dependence on taking pills every day - only a few injections and boosters
- Progress towards a possible permanent "functional cure" for HIV/AIDS

Study Findings – The Details

The findings from the study indicate:

- VRX1273 fully achieved the primary objective of meeting the FDA's pre-requisites for moving forward to the clinic, as it elicits a strong immune response to the virus.
- A subset of the vaccinated rhesus macaques achieved a "functional cure" based on the following criteria:
 - controlling the SIV viral load to low or undetectable levels for a sustained period of time, and even continuing beyond of the 18 month study (a unique finding considering the stringency of the SIV challenge used),
 - decreasing the quantity of the SIV hiding in cells both in circulation and in reservoirs (the frequency of cells harboring an integrated SIV genome in their nucleus is now very low or undetectable in circulating blood cells and in cells present in the gut and lymph nodes.), and
 - preserving and enhancing the immune compartment as measured by the level and frequency of CD4 T lymphocytes (the cells that are naturally destroyed by SIV in rhesus macaques), and improving long-term survival.
- These achievements were reached for a period as long as two years after the last vaccination, with no booster administrations.

VRX1273 Strategy – The Lentiviral Vector

HIV is one of a class of viruses known by researchers as "lentivirus." VIRxSYS uses an extensively engineered lentiviral vector to create our therapeutic HIV vaccine. The Company's lentiviral vectors are directly derived from HIV: the HIV genome has been "guttled," removing all disease-causing elements and preserving only its desirable features. Like HIV itself, the modified lentivirus is highly capable of entering human cells and can stably persist in those cells. The Company believes that creating an HIV vaccine with a HIV-derived vector has a logical elegance to it - providing the vaccine with all the elements to fight HIV on similar grounds.

Safety and experience with the Lentiviral Vector

Since the Company's inception 13 years ago, VIRxSYS has developed an unparalleled expertise in the design and manufacture of clinical grade HIV-based lentiviral vectors for human therapies. VIRxSYS' VRX496® was the first HIV-based lentiviral vector product tested in humans.

VRX496 CD4 T cell-based RNA immunotherapy is an *ex-vivo*, autologous cell based therapy that has been infused into 65 HIV infected individuals in the course of several Phase I and Phase II clinical studies - this represents the largest cohort ever infused with a cell product modified with a lentiviral vector.

From these studies, VIRxSYS accumulated over 300 patient-years of safety data without recording a single serious adverse event related to the product. A presentation of VRX496 will be also done during the International AIDS Society Conference.

Data from the VRX1273 study will also be discussed at a Conference satellite symposium, NAPWAs' Treatment Horizons: Pathways to a Functional Cure, Tuesday, July 19th from 7:00am to 8:30am, CEST.

About VIRxSYS

VIRxSYS Corporation is a biotechnology company with platform technologies focused on the development of novel therapies for serious human diseases. The Company's proprietary platforms include: (i) lentiviral vectors as vaccines and curative gene delivery vehicles to the core of human cells, and (ii) RNA *trans*-splicing for the repair and reprogramming of genes. More information can be found at www.virxsys.com.

Forward-Looking Statements

This release may contain forward-looking statements regarding VIRxSYS Corporation's activities. Any such forward-looking statements involve, and are subject to, many known and unknown risks and uncertainties common to any drug or therapy development company, including, but not limited to, whether development efforts will succeed, whether products will receive regulatory approval, and whether products will achieve commercial success. Such risks and uncertainties could cause VIRxSYS' actual results, performance or achievements to be different from those anticipated and such differences could be material. Further, any forward-looking statements contained in this release are made only as of the date it was created, and VIRxSYS expressly disclaims any obligation to update any such forward-looking statements, whether as a result of new information, future events, or otherwise.

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