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## Product Discovery & Development

# HIV Trojan horse

By Michael Flanagan  
Senior Writer

HIV's ability to hide out in the body in places that drugs can't reach has helped the virus remain resistant to eradication. But **Virxsys Corp.** thinks its VRX1273 may be able to provide a functional cure for some patients by reaching all the walls into these disease reservoirs.

The therapeutic T cell vaccine hijacks HIV's ability to infect cells by gutting the virus and using it as the vector. The compound produced functional cures in 40% of monkeys 18 months after a viral challenge, according to data presented last month.

"For the last several years the idea of a functional cure for AIDS has been gaining increasing interest among key opinion leaders," according to Lawrence Michaelis, chairman and interim president and CEO of Virxsys.

By functional cure, he envisions a therapy that knocks down viral load such that a patient's immune system can keep it in check. This would decrease the need for other drugs and increase survival.

Michaelis believes this is possible using VRX1273. The disease-causing elements have been removed from the vector and replaced inside VRX1273 with three HIV antigens — gag, pol and rev — that are designed to stimulate an immune response.

"The HIV vector has a tremendous ca-

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Lawrence Michaelis, Virxsys

capacity for entering cells, and what we do with it in terms of modifying the envelope of the gene means the body recognizes it as HIV and turns on CD4 and CD8 T cells to mount an attack. But at the same time it is actually a totally benign virus," he said.

In the study reported last month, 10 rhesus macaques received three subcutaneous injections of either VRX1116, a simian analog of VRX1273, or placebo over six months before being infected with a high dose of simian immunodeficiency virus (SIV).

Two of the five vaccinated monkeys had undetectable viral levels 18 months after the SIV challenge. Results were presented at the annual **International AIDS Society** Conference on HIV Pathogenesis, Treatment, and Prevention in Rome.

"These full responders to the vaccine had undetectable levels of the virus in the blood, their immune compartments [of CD4 cells] were fully preserved, and they had significantly better survival than the control group," said Michaelis.

Perhaps the most important observation, he noted, was that VRX1273 administration resulted in "very low to undetectable levels of the virus in the lymphatic and intestinal reservoirs where 90% of HIV in the body resides."

Michaelis suggested this is the first time an HIV vaccine has demonstrated this level of activity in eradicating the virus in the lymph nodes and gut, traditional hotspots of viral replication.

The next step is to see if the efficacy translates into humans.

Michaelis said Virxsys has been talking to FDA about the IND package and aims to move into a Phase I trial in 12-15 months.

The company hopes to receive financial support from groups such as the **AIDS Clinical Trials Group** and the **National Institutes of Health**.

#### COMPANIES AND INSTITUTIONS MENTIONED

**AIDS Clinical Trials Group**, Rockville, Md.  
**International AIDS Society**, Geneva, Switzerland  
**National Institutes of Health**, Bethesda, Md.  
**Virxsys Corp.**, Gaithersburg, Md.

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