

## ImmunoGenetix's HIV Vaccine Therapy Nears Pre-IND Work

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Staff Writer

Failed attempts litter the development path for HIV vaccines, but **ImmunoGenetix** Therapeutics Inc. believes its DNA-based approach may pack the potent punch that others have lacked.

The Lenexa, Kan.-based company was founded on research conducted by Opendra Narayan, director of the Marion Merrell Dow Laboratory of Viral Pathogenesis at the University of Kansas Medical Center. Narayan, who serves on **ImmunoGenetix's** scientific advisory board, created a DNA vaccine called GenePro that uses a simian HIV vector to deliver six of the nine genes comprising HIV.

James Laufenberg, **ImmunoGenetix's** president and CEO, pointed out that GenePro is a therapeutic vaccine, while many HIV vaccines that previously failed were focused on prevention. The preventative approach has thus far been thwarted because HIV quickly destroys the cells needed to mount an immune response and attacks immunological memory cells, wiping out long-term immunity. One of the most advanced preventative HIV vaccines, South San Francisco-based VaxGen Inc.'s AIDSvax, failed two Phase III trials. (See *BioWorld Today*, Feb. 25, 2003 and Nov. 13, 2003.)

GenePro is also differentiated from past failed attempts by its DNA-based construct, which **ImmunoGenetix** said may offer stronger efficacy than whole-killed or recombinant approaches. Orchestra Therapeutics Inc. (formerly Immune Response Corp.), of Carlsbad, Calif., discontinued its HIV vaccine program earlier this year after failures with the whole-killed vaccines Remune and IR103. (See *BioWorld Today*, July 19, 2007.)

And among the other DNA vaccines, GenePro boasts a unique vector, aggressive promoter and more HIV genes, Laufenberg said. By comparison, Whitehouse Station, N.J.-based Merck & Co. Inc.'s V520, which was halted in Phase II last month due to lack of efficacy, contained three HIV genes. Laufenberg said the three genes excluded from GenePro were deleted for safety reasons. "In our opinion, this is as aggressive as you'd want to get," he said.

In a study published last year in *Virology*, all 12 HIV-infected macaques treated with GenePro (previously referred to as Delta4SHIVku2) demonstrated control of virus replication, with plasma viral loads dropping to undetectable levels between weeks six and 126 following intramuscular injection. All seven control animals developed a progressive infection.

Although **ImmunoGenetix** was founded in 2001, the company originally focused on cardiovascular disease. Laufenberg helped put together a re-launch in 2003, and said he was drawn to the HIV work because existing anti-retroviral drugs "have been a godsend but are not without their problems."

Those problems include often complex dosing regimens and emerging side effects associated with long-term use. Laufenberg said **ImmunoGenetix's** goal is to see patients stabilized on antiretroviral drugs and then use GenePro every three months to "give them a drug holiday."

Even after its re-launch, **ImmunoGenetix** has stayed largely off the radar, operating as a virtual company on \$1.2 million of seed money obtained from angels and Kansas Technology Enterprise Corp.

That money went toward establishing a patent estate, but Laufenberg said the company is now in the process of raising \$4 million to conduct investigational new drug-enabling studies, scale up manufacturing, and meet with the FDA. While he'd "love to invite venture capitalists to participate because of their expertise," Laufenberg said he believes he can raise the money locally through angels, economic development programs, and a small, local venture fund.

The financing is expected to close by the end of the year so that pre-IND work can begin in early 2008.

After that, **ImmunoGenetix** plans to conduct a Phase I trial of about 40 patients, which Laufenberg said will look at some "interesting markers" to demonstrate immune response in addition to standards like CD4 and viral load.

As to whether or not **ImmunoGenetix** will seek a development partner, Laufenberg said the company is "certainly open to a partnership" but for now plans to "keep our knees bent and stay flexible."

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