GeoVax Vaccine to Treat HIV Enters Human Clinical Trial

March 31, 2010

GeoVax Labs has been given the green light by the U.S. Food and Drug Adiministration (FDA) to begin studying its therapeutic vaccine candidate in a Phase I clinical trial involving people living with HIV, according to a press release from the company. The non-blinded study, to be conducted at the AIDS Research Consortium of Atlanta (ARCA), will test the vaccine in HIV-positive individuals who started drug treatment during the first year of infection.

Therapeutic HIV vaccines are designed to boost the body's immune response to HIV in order to better control the infection. Though it is unlikely that therapeutic vaccines will be able to eradicate HIV from the body, they may be able to prime the immune system enough to either delay the need for antiretroviral (ARV) therapy or to stop HIV treatment indefinitely.

"Based upon preclinical animal data," said Robert McNally, PhD, president and CEO of GeoVax, "we believe our therapeutic vaccine may improve treatment options for people infected with HIV and are delighted we will be able to begin a Phase I clinical trial."

The results of animal studies exploring GeoVax's therapeutic vaccine were reported by the company in July 2008. The compound was tested in two simian immunodeficiency virus (SIV)–infected primates.

At 12 weeks post-SIV infection, ARV therapy was given to the primates to reduce SIV replication, then the vaccine was administered. Six weeks following the final vaccination, ARV treatment was stopped and the animals were monitored to determine whether the vaccine could control SIV infection while off therapy.

According to GeoVax, the vaccine proved highly beneficial. In one primate, there was a thousand-fold reduction in viral levels over pre-ARV treatment. In the other, there was a hundred-fold reduction in pre-treatment viral levels.

The excellent control of SIV in the absence of ARV treatment, the company reported, was associated with the vaccine raising the types of CD4 and CD8 cells found in "elite controllers"—a small number of HIV-positive individuals capable of keeping their viral loads low without ARV therapy.

The protocol for the Phase I clinical trial, conceived in collaboration with ARCA, will carefully monitor safety while evaluating the vaccine's ability to elicit protective immune responses in vaccinated participants. For the next step, ARCA will submit trial documentation to the Institutional Review Board for local review, a standard requirement to protect human subjects.

“An unmet need exists in the market for a HIV therapeutic vaccine if it can reduce the need for expensive and poorly tolerated lifelong oral medications currently available to infected individuals,” McNally said. “We also recognize that this trial will enable GeoVax to gather crucial information toward our vaccine’s success on a more timely basis than the time required to perform a preventive trial.”

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