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HIV drug tests set for Phase 2

More hurdles ahead, but Atlanta's GeoVax says its vaccine shows 'significant promise.'

By [Bill Hendrick](#)

The Atlanta Journal-Constitution

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Despite the failure last fall of Merck & Co.'s AIDS vaccine, a fledgling Atlanta biotechnology company, GeoVax Inc., is charging ahead into advanced tests of a new drug that it says shows "significant promise."

"We've had excellent results in our early stage human trials," said Emory University's Harriet Robinson, leader of a team of scientists working on the vaccine.

Its vaccine is the only one of several being developed that is on the verge of being moved into Phase 2 tests by the HIV Vaccine Trials Network, which is supported by the National Institutes of Health. GeoVax's trials are expected to start this summer.

GeoVax is a publicly owned company and an Emory University spinoff.

Merck's vaccine failed to meet objectives to protect trial participants from HIV infection and appeared to make some people more likely to contract the virus. The company said last fall that it pulled the plug on its vaccine because it "did not deliver on the promise."

GeoVax uses different methods in its vaccine production and won't run into the same difficulties, said Bob McNally, president and chief executive of GeoVax and a biotechnology scientist.

"The upcoming Phase 2 trial is being conducted in a larger number of healthy individuals," McNally said. "Now that the delivery combinations of the vaccine have been worked out, the Phase 2 trial will expand the participants to 150 vaccinated volunteers and 75 volunteers as a control group who do not receive the vaccine."

The volunteers are not at risk for contracting AIDS, he said, but the objective is to measure the T-cell and antibody response to the vaccine in normal volunteers.

"The significance of the results will be to give a level of comfort to the [U.S. Food and Drug Administration] and GeoVax that when this vaccine is used in at-risk volunteers, there will be a high degree of likelihood that the patients will be protected from contracting the disease," he said.

Robinson said her hope is that GeoVax's vaccine may one day be administered to adolescents.

Mitchell Warren, executive director of the nonprofit AIDS Vaccine Advocacy Coalition in New York, said the firm's advancement to Phase 2 represents significant progress.

"Their Phase 1 data is compelling and warrants taking [the vaccine] into Phase 2," he said. "But there is still much more to be done."

That means the company is closer but still must get through several more steps, including Phase 2, which like Phase 1 will involve people at relatively low risk of contracting HIV, he said.

"You are not looking for efficacy in these trials," he said. "That comes later in much larger trials. With GeoVax, they're still in the early phases of product development. The early data look good. If it looks good after Phase 2, it will go into Phase 3. There are still a number of more hurdles."

Several products have advanced to Phase 2 trials, and two of three that advanced to Phase 3 have failed, he said.

The purpose of Phase 2 trials is to make sure the vaccine is safe for people who are not at high risk for HIV, he said. Beyond that point, Warren said, the vaccine would still go to larger efficacy testing in high-risk people before it could be presented to the FDA or other regulatory body for possible licensing.

GeoVax, like other companies, faces hurdles, but it is still in the race.

Robinson noted that no vaccine has ever prevented infection, but she has high hopes GeoVax's will "prevent the development of disease and transmission."

McNally said Robinson "would like it to be perfect, to protect 100 percent of the population. But let's say it does 60 percent, or 50 percent. Whatever that number is better than what we have now."

"The current polio vaccine only protects 70 percent," Robinson added, "but polio has been eradicated from the United States."

Don Hildebrand, board chairman of GeoVax, said "only a handful of AIDS vaccines have reached" the same level of evaluation as GeoVax's.

Robinson's vaccine has shown encouraging results.

She and a team of scientists at the Yerkes National Primate Research Center at Emory conducted a test on rhesus monkeys using a simian-human version of her HIV vaccine. It protected 96 percent of at-risk monkeys for more than three years.

The upcoming trials will suggest whether the human vaccine is likely to perform as effectively as it did in the monkeys. It works by making HIV proteins to prime the body's immune system.

Robinson and McNally said they have high hopes for the vaccine, but they noted that premature cures have been announced many times in the past for other diseases and they're not going to let that happen with the GeoVax product.

Various sources ranging from the Centers for Disease Control and Prevention to the White House have their own estimates of the number of people worldwide who have died of AIDS, ranging from 22 million to more than 25 million.

More than 550,000 people with AIDS have died in the United States since the early 1980s, and more than 16,000 in Georgia, according to the CDC. The agency said 449,000 Americans were living with AIDS in 2006.

GeoVax is one of a handful of publicly owned firms in Georgia's biotechnology industry, which employs about 15,000 people and has a payroll of about \$1 billion. It is estimated there are about 250 companies in the life sciences sector.

The company has 730 million shares outstanding, 30 percent of which are owned by Emory. Robinson and Hildebrand, the co-founders, own 10 percent, and the rest is owned by several thousand other investors, McNally said.

"Commercial biological research, the core of what is thought of popularly as 'biotech,' has begun to blossom in Georgia thanks in large part to a rapidly expanding bioscience research base assembled around several world class research universities in the state," said C. Michael Cassidy, president of the Georgia Research Alliance.

ABOUT GEOVAX

> Founded: 2001

> Employees: 15

> Shares outstanding: 730 million

> Type of company: biotechnology

> Company officers

Robert T. McNally, Ph.D., president & CEO

Harriet L. Robinson, Ph.D., senior vice president

Donald G. Hildebrand, chairman, board of directors

Mark W. Reynolds, CFO & secretary

Andrew J. Kandalepas, senior vice president

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