

# **NewLink Genetics: Ready to test Ebola vaccine (Update 3)**

August 14 2014, by Tom Murphy

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An Iowa drug developer is preparing to test a possible Ebola vaccine in humans, as scientists race to develop ways to prevent or fight a virus that has killed more than 1,000 people in a West African outbreak.

NewLink Genetics is planning an initial phase of testing involving up to 100 healthy volunteers and is talking with regulators about the study, said Brian Wiley, the company's vice president for business development. He declined to say whether the drug developer has submitted an application for the research to the Food and Drug Administration.

Chief Financial Officer Gordon Link said Thursday the timing of the testing, which would involve up to 100 healthy volunteers, is uncertain.

"We're getting a lot of assistance from a number of sources to accelerate this, so exactly how long it's going to take is a little uncertain because people are greasing the paths as much as they can," he said.

There is no proven treatment or vaccine for Ebola, and the current outbreak, which also has sickened nearly 2,000 people, is the largest in history. The outbreak was first detected in March in Guinea and spread to Liberia, Sierra Leone and Nigeria.

Other possible Ebola vaccines under development include one developed at the National Institutes of Health that is set to begin early-stage testing in humans this fall.

On Wednesday, Canadian drugmaker Tekmira Pharmaceuticals Corp. said it wasn't ready to make its experimental Ebola drug available in Africa.

NewLink Genetics Corp. is planning to test a vaccine that was discovered by scientists working for the Canadian government. The U.S. drugmaker has an exclusive license to take it through clinical trials and then sell it if regulators grant approval.

NewLink said the vaccine has been 100 percent effective in preventing deadly Ebola infections in non-human primates, and it acts quickly enough to show effectiveness in animals that received a typically lethal dose of the virus.

The vaccine contains an antigen from the Ebola virus, and it essentially teaches a person's immune system how to fight the virus.

"This is a very traditional vaccination process," said Dr. Nicholas Vahanian, NewLink's chief medical officer.

Researchers will be focused mainly on the vaccine's safety in the initial round of testing, but they also will measure the antibodies the subject's body produces to fight the virus.

"By measuring their immune response to the vaccine, you can predict the effectiveness," Vahanian said.

The company also is working to line up manufacturing partners to make additional doses of the vaccine.

"It is not a particularly challenging vaccine to manufacture," Vahanian said. "We are expending all our efforts to be able to secure additional manufacturing partners so we can meet high demand."

A total of 1,500 doses have already been produced by a contract manufacturer in Germany, and the Canadian government purchased all of them. The government is setting aside some for NewLink to use in clinical research, and it also plans to donate between 800 and 1,000 doses to the World Health Organization, which is coordinating the international response to the latest outbreak.

Earlier this month, NewLink, which has no products on the market, announced a \$1 million contract with the U.S. Defense Threat Reduction Agency to help fund research leading up to the human testing.

Shares of the Ames, Iowa, company soared almost 12 percent, or \$2.73, to \$26.17 in trading Thursday, while broader indexes rose less than 1 percent.

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