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NIH begins early human clinical trial of VSV Ebola vaccine

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Human testing of a second investigational Ebola vaccine candidate is under way at the National Institutes of Health's Clinical Center in Bethesda, Maryland.

Researchers at the National Institute of Allergy and Infectious Diseases (NIAID) are conducting the early phase trial to evaluate the vaccine, called VSV-ZEBOV, for safety and its ability to generate an immune system response in healthy adults who are given two intramuscular doses, called a prime-boost strategy. The Walter Reed Army Institute of Research (WRAIR) is simultaneously testing the vaccine candidate as a single dose at its Clinical Trials Center in Silver Spring, Maryland.

"The need for a vaccine to protect against Ebola infection is urgent," said NIAID Director Anthony S. Fauci, M.D. "NIH welcomes the opportunity to collaborate with the U.S. Department of Defense to conduct human clinical tests of another promising—and hopefully, successful—Ebola vaccine candidate."

NIAID researchers include principal investigator Richard T. Davey, M.D., and co-investigator John Beigel, M.D., of NIAID's Division of Intramural Research.

Early human testing of another investigational Ebola vaccine co-developed by NIAID and GlaxoSmithKline (GSK) began in early September. Initial data on safety and immunogenicity (the capacity to generate an immune response) from clinical trials of the NIAID/GSK

Ebola vaccine are expected by the end of 2014.

The VSV-ZEBOV vaccine candidate was developed by researchers at the Public Health Agency of Canada's National Microbiology Laboratory. It has been licensed to NewLink Genetics Corp through its wholly owned subsidiary BioProtection Systems, both based in Ames, Iowa.

"Canada has long been a world leader in Ebola research and innovation. Scientists at Canada's National Microbiology Lab developed this Ebola vaccine, following years of hard work. We hope the clinical trial at the National Institutes of Health proves to be safe and effective, so that the Canadian Ebola vaccine can be used as a global resource to help save lives and end this complex outbreak in West Africa," said Canada's Minister of Health Rona Ambrose.

"We are pleased to recognize the extraordinary work of our partners to move the VSV-ZEBOV vaccine candidate from preclinical development to clinical testing in a matter of weeks rather than years. This level of support has been and will continue to be a critical asset in the ongoing process of evaluating and potentially bringing this investigational product to broader use in the fight against Ebola virus," said Charles Link, M.D., chief scientific officer and CEO, NewLink Genetics.

VSV-Zebov is based in part on a genetically engineered version of vesicular stomatitis virus (VSV), which primarily affects rodents, cattle, swine and horses. Human VSV infections are rare and generally produce three to four days of mild illness. In the VSV-ZEBOV investigational vaccine, the gene for the outer protein of the vesicular stomatitis virus has been replaced with a segment of the gene for the outer protein of the Zaire Ebola virus species. The investigational VSV-ZEBOV vaccine cannot cause a vaccinated individual to become infected with Ebola.

The NIH Phase 1 clinical trial of the VSV-ZEBOV vaccine candidate will enroll 39 healthy adults aged 18 to 65 years. Participants will be randomly assigned to one of three groups with 13 participants each. In each group, 10 participants will receive the investigational VSV-ZEBOV vaccine; three will receive a placebo. Each of the three groups will receive a different, escalating dose of the investigational vaccine, with the first group enrolled receiving the lowest dose and the third group enrolled receiving the highest dose. Study participants will receive an injection of the VSV-ZEBOV vaccine or placebo at their first scheduled visit and again, at the same dosage level, 28 days later.

Enrollment at each dosing level is staggered, so interim safety assessments of vaccinated individuals can be conducted before moving to the next dosing level. All study participants will be seen and evaluated by clinical staff 11 times over one year.

While NIAID tests the VSV-ZEBOV vaccine candidate as a prime-boost strategy, WRAIR is evaluating the investigational vaccine as a single injection. This is being done to evaluate in real time the safety profile of the investigational vaccine when provided at different dosages and compare the immune responses induced by one injection versus two injections. Initial safety and immune response data on the VSV-ZEBOV vaccine are expected by the end of 2014.

Provided by NIH/National Institute of Allergy and Infectious Diseases