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United States Army Medical Research Institute of Infectious Diseases
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Smallpox Vaccine Study Yields Favorable Results

Research Paves Way for Replacing Current U.S. Licensed Vaccine

Officials from Bavarian Nordic yesterday announced the results of a successful Phase 3 clinical trial led by USAMRIID that demonstrated the safety and efficacy of the company's investigational, non-replicating smallpox vaccine, IMVAMUNE®.

The product is being developed as an alternative to the current U.S. licensed replicating smallpox vaccine, ACAM2000®, which cannot be used by certain populations, including people with atopic dermatitis and HIV. It is already approved in Canada and the European Union.

USAMRIID study director Phillip R. Pittman, M.D., collaborated with the U.S. Defense Health Agency to enroll 440 subjects at a U.S. military post in South Korea. The randomized, open-label study had two co-primary endpoints. The first was to show that IMVAMUNE induced a non-inferior antibody response when compared with ACAM2000. In this study, the peak neutralizing antibodies induced by IMVAMUNE were shown to be twofold higher than those stimulated by ACAM2000, demonstrating a statistically superior immune response.

The second co-primary endpoint was to demonstrate an attenuation or prevention of a "take" in volunteers previously vaccinated with IMVAMUNE. Historically, a take is a measure of efficacy against smallpox in people vaccinated for the first time. It consisted of a pustule, scab and scar that developed on the skin following initial vaccination with replicating smallpox vaccines like ACAM2000. Following the second vaccination, those who had developed a protective immune response showed either a reduced take or none at all. This also was achieved in the USAMRIID-Bavarian Nordic study.

"If approved, this vaccine will have a direct impact on improving force health protection for U.S. Soldiers and other service members who are required to be immunized against smallpox," said COL Gary Wheeler, commander of USAMRIID.

According to Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic, IMVAMUNE has been given to more than 7,800 subjects in 21 clinical studies, including this trial and

one other Phase 3 study. He said the company plans to file a Biological License Application with the U.S. Food and Drug Administration later this year.

"This program has only been possible through the consistent and strong support of numerous U.S. Government agencies and demonstrates what can be achieved through a successful public-private partnership to protect the public from the deliberate release of the smallpox virus," Chaplin added.

Funding for the study was provided by the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100200700034C. Study details are available at https://clinicaltrials.gov/ct2/show/NCT01913353. For more information about Bavarian Nordic, visit www.bavarian-nordic.com.

USAMRIID's mission is to provide leading edge medical capabilities to deter and defend against current and emerging biological threat agents. Research conducted at USAMRIID leads to medical solutions—vaccines, drugs, diagnostics, and information—that benefit both military personnel and civilians. The Institute plays a key role as the lead military medical research laboratory for the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command. For more information, visit www.usamriid.army.mil.

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