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## **New Smallpox Vaccine Tested by USAMRIID Receives FDA Approval**

Army scientists played a key role in testing a new smallpox vaccine approved last week by the U.S. Food and Drug Administration. Marketed under the brand name JYNNEOS, the product, developed by Bavarian Nordic, is a live, non-replicating vaccine for the prevention of both smallpox and monkeypox disease in adults.

“In addition to its public health importance, this vaccine will have a direct impact on improving force health protection for U.S. service members who are required to be immunized against smallpox,” said Col. E. Darrin Cox, commander of the U.S. Army Medical Research Institute of Infectious Diseases.

Thanks to the success of a worldwide smallpox vaccination program, the World Health Assembly declared the disease eradicated in 1980. With a large proportion of the world’s population no longer immune to smallpox, however, an intentional release of the virus could have a devastating global impact. Current smallpox research focuses on developing vaccines, drugs and diagnostic tests to protect people against the virus should it be used as an agent of bioterrorism.

According to Bavarian Nordic officials, JYNNEOS was 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. JYNNEOS is currently the only FDA-approved vaccine for the prevention of monkeypox disease.

To assess the vaccine’s effectiveness, USAMRIID study director Phillip R. Pittman, M.D., led a pivotal Phase 3 clinical trial in collaboration with the U.S. Defense Health Agency. His team enrolled U.S. service members stationed in South Korea for a randomized, open-label study that placed 440 participants into one of two groups. Group 1 received two doses of JYNNEOS 28 days apart, while Group 2 received only a single dose of ACAM2000, and the immune responses were subsequently compared.

The group vaccinated with JYNNEOS had an immune response that was non-inferior to immune responses to ACAM2000. In fact, according to Pittman, the peak neutralizing antibodies induced by JYNNEOS were shown to be twofold higher than those stimulated by ACAM2000, demonstrating a statistically superior immune response.

FDA officials said the new smallpox vaccine is part of the Strategic National Stockpile, the nation’s largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health

emergency. The availability of this vaccine in the stockpile will help ensure that the vaccine is accessible in the U.S. if needed.

JYNNEOS is made from vaccinia virus, which is closely related to smallpox and monkeypox but is less harmful and can be used to protect against both diseases. JYNNEOS contains a modified form of the vaccinia virus called Modified Vaccinia Ankara, which does not cause disease in humans and is non-replicating, meaning it cannot reproduce in human cells.

“The FDA approval of JYNNEOS is a tremendous milestone for both our company and the U.S. government,” said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic. “Together, we have shown that it is possible to develop a safe and effective medical countermeasure for national security threats like smallpox. JYNNEOS is the culmination of a fifteen-year partnership with numerous agencies across the U.S. government, including USAMRIID, who played a pivotal role in conducting the final clinical study to support the registration of the vaccine. We are committed to the continued supply of vaccines to the U.S. and thank them for their global leadership on biodefense.”

The USAMRIID-led Phase 3 clinical trial was funded in full by a Cooperative Research and Development Agreement with Bavarian Nordic.

### **About Smallpox**

Smallpox is an ancient disease, caused by the variola virus, which is highly contagious and often fatal in humans. Symptoms include fever, body aches, and a skin rash that develops into fluid-filled lesions. The smallpox virus is spread through saliva and droplets from the respiratory tract, or by direct or indirect contact with the virus as it is shed from skin lesions. The virus also can be spread through other body fluids and contaminated clothing or bedding.

### **About Monkeypox**

Monkeypox, which does not occur naturally in the U.S., is a rare disease caused by infection with monkeypox virus. It begins with fever, headache, muscle aches and exhaustion and can be fatal in some cases, although it is typically milder than smallpox. Monkeypox is transmitted to people from wild animals, such as rodents and primates. In 2003, the U.S. experienced an outbreak of monkeypox, marking the first time human monkeypox was reported outside of Africa.

### **About USAMRIID**

USAMRIID is celebrating its 50th year of providing leading edge medical capabilities to deter and defend against current and emerging biological threat agents. The Institute is the only laboratory in the Department of Defense equipped to safely study highly hazardous viruses requiring maximum containment at Biosafety Level 4. Research conducted at USAMRIID leads to medical solutions—vaccines, drugs, diagnostics, and information—that benefit both military personnel and civilians. Established in 1969, 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 Development Command. For more information, visit [www.usamriid.army.mil](http://www.usamriid.army.mil).

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