

FDA NEWS RELEASE

FDA approves first live, non-replicating vaccine to prevent smallpox and monkeypox

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September 24, 2019

The U.S. Food and Drug Administration announced today the approval of Jynneos Smallpox and Monkeypox Vaccine, Live, Non-Replicating, for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. This is the only currently FDA-approved vaccine for the prevention of monkeypox disease.

“Following the global Smallpox Eradication Program, the World Health Organization certified the eradication of naturally occurring smallpox disease in 1980. Routine vaccination of the American public was stopped in 1972 after the disease was eradicated in the U.S. and, as a result, a large proportion of the U.S., as well as the global population has no immunity,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research. “Therefore, although naturally occurring smallpox disease is no longer a global threat, the intentional release of this highly contagious virus could have a devastating effect. Today’s approval reflects the U.S. government’s commitment to preparedness through support for the development of safe and effective vaccines, therapeutics, and other medical countermeasures.”

Jynneos will be available for those determined to be at high risk of either smallpox or monkeypox infection. This vaccine is also part of the Strategic National Stockpile (SNS), the nation’s largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency that is severe enough to cause local supplies to be depleted. The availability of this vaccine in the SNS will help ensure that the vaccine is accessible in the U.S. if needed.

Smallpox, which is caused by the variola virus, emerged in human populations thousands of years ago and is a highly contagious and often fatal infectious disease. A person infected with smallpox typically develops a rash characterized by raised pocks on the face and body. 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 can also be spread through other body fluids and contaminated clothing or bed linen. If a person is infected with smallpox and they are in close contact with others, the virus can spread quickly.

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

Jynneos does not contain the viruses that cause smallpox or monkeypox. It is made from a vaccinia virus, a virus that is closely related to, but less harmful than, variola or monkeypox viruses and can protect against both of these 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 effectiveness of Jynneos for the prevention of smallpox was determined in a clinical study comparing the immune responses in study participants who received either Jynneos or ACAM2000, an FDA-approved vaccine for the prevention of smallpox. The study included approximately 400 healthy adults, 18 through 42 years of age who had never been vaccinated for smallpox, in which half of the study participants received two doses of Jynneos administered 28 days apart, and half received one dose of ACAM2000. The group vaccinated with Jynneos had an immune response that was not inferior to immune responses to ACAM2000. Vaccine effectiveness for the prevention of smallpox was also inferred from supportive animal studies that showed prior vaccination with Jynneos protected non-human primates who were exposed to viruses related to the smallpox virus.

The effectiveness of Jynneos for the prevention of monkeypox disease is inferred from the antibody responses in the smallpox clinical study participants and from studies in non-human primates that showed protection of animals vaccinated with Jynneos who were exposed to the monkeypox virus.

The safety of Jynneos was assessed in more than 7,800 individuals who received at least one dose of the vaccine. The most commonly reported side effects were pain, redness, swelling, itching, firmness at the injection site, muscle pain, headache and fatigue. No safety concerns that would require a Medication Guide have been identified for Jynneos. Jynneos is administered in two doses given four weeks apart.

The FDA granted the approval of Jynneos to Bavarian Nordic A/S. The FDA granted the application [Priority Review \(/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review\)](#) and with this approval, the FDA issued a material threat medical countermeasure (MCM) priority review voucher to Bavarian Nordic A/S. The Federal Food, Drug, and Cosmetic Act, as amended by the 21st Century Cures (Cures) Act, authorizes the FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Related Information

- FDA - [Licensed Vaccines \(/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states\)](#)
- FDA - [Priority Review \(/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review\)](#)
- FDA - [Smallpox Preparedness and Response Updates from FDA \(/emergency-preparedness-and-response/mcm-issues/smallpox-preparedness-and-response-updates-fda\)](#)
- FDA - [21st Century Cures Act: MCM-Related Cures Provisions \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions\)](#) (including the MCM priority review voucher program)
- HHS - [Strategic National Stockpile \(https://www.phe.gov/about/sns/Pages/default.aspx\)](https://www.phe.gov/about/sns/Pages/default.aspx)

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