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FDA approves vaccine for prevention of smallpox, monkeypox

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Jynneos Smallpox and Monkeypox Vaccine, Live, Non-Replicating, was

approved by the U.S. Food and Drug Administration for prevention of smallpox and monkeypox disease in adults 18 years or older who are considered at high risk for infection, the agency announced this week.

Jynneos, which is administered in two doses four weeks apart, contains Modified Vaccinia Ankara, a form of the vaccinia virus closely related to the variola or monkeypox viruses but less harmful. To ensure it is accessible in the United States if needed, Jynneos is part of the Strategic National Stockpile, a national supply of pharmaceuticals and medical supplies for use in a public health emergency that depletes local supplies.

Approval of Jynneos for prevention of smallpox was based on data from a clinical study comparing the immune responses of 400 healthy adults (ages 18 to 42 years) who received two doses of Jynneos 28 days apart or one dose of ACAM2000, an FDA-approved vaccine for smallpox prevention. None of the patients had been previously vaccinated for smallpox. The immune response of individuals vaccinated with Jynneos was not inferior to that of individuals vaccinated with ACAM2000.

Approval of Jynneos for prevention of monkeypox was based on the antibody responses of the smallpox clinical study participants as well as data from nonhuman primate studies demonstrating protection of animals vaccinated with Jynneos when they were exposed to the monkeypox virus. Safety data from more than 7,800 individuals who received at least one dose revealed the most commonly reported side effects were pain, redness, swelling, itching, firmness at the injection site, muscle pain, headache, and fatigue.

"Although naturally occurring smallpox disease is no longer a global threat, the intentional release of this highly contagious virus could have a devastating effect," Peter Marks, M.D., Ph.D., director of the FDA Center for Biologics Evaluation and Research, said in a statement.

Approval was granted to Bavarian Nordic A/S.

More information: More Information

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