Jynneos™ (smallpox and monkeypox vaccine, live, nonreplicating) – New drug approval

- On September 24, 2019, the FDA announced the approval of Bavarian Nordic's Jynneos (smallpox and monkeypox vaccine, live, nonreplicating), for prevention of smallpox and monkeypox disease in adults18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

- Smallpox, which is caused by the variola virus, 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.

- 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 is the only currently FDA-approved vaccine for the prevention of monkeypox disease.

    — 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.

- The vaccine effectiveness of Jynneos against smallpox was inferred by comparing the immunogenicity of Jynneos to a FDA-approved smallpox vaccine (ACAM2000) and was supported by efficacy data from animal challenge studies. In an immunogenicity study of 433 patients, the group vaccinated with Jynneos had an immune response that was not inferior to immune responses to ACAM2000.

- The vaccine effectiveness of Jynneos against monkeypox disease was 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.

- Warnings and precautions for Jynneos include severe allergic reactions, altered immunocompetence, and limitations of vaccine effectiveness.

- In smallpox vaccine-naïve healthy adults, the most common (> 10%) solicited injection site reactions were pain (84.9%), redness (60.8%), swelling (51.6%), induration (45.4%), and itching (43.1%); the most common solicited systemic adverse reactions were muscle pain (42.8%), headache (34.8%), fatigue (30.4%), nausea (17.3%) and chills (10.4%).

- In healthy adults previously vaccinated with a smallpox vaccine, the most common (> 10%) solicited injection site reactions were redness (80.9%), pain (79.5%), induration (70.4%), swelling (67.2%), and itching (32.0%); the most common solicited systemic adverse reactions were fatigue (33.5%), headache (27.6%), and muscle pain (21.5%).

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- The recommended dose of Jynneos is two doses (0.5 mL each) administered subcutaneously 4 weeks apart.

- Bavarian Nordic's launch plans for Jynneos are pending. Jynneos will be available as a suspension for injection (0.5 mL single-dose vials).