

Approval Date: [September 24, 2019](#)

Product: JYNNEOS

Proper Name: Smallpox and Monkeypox Vaccine, Live, Non-Replicating

Manufacturer: Bavarian Nordic A/S

Indication: JYNNEOS is a vaccine indicated for 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.

Description: When thawed, JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Non-replicating) is a milky, light yellow to pale white colored suspension for subcutaneous injection. JYNNEOS is a live vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus. MVA-BN is grown in primary Chicken Embryo Fibroblast (CEF) cells suspended in a serum-free medium containing no material of direct animal origin, harvested from the CEF cells, purified and concentrated by several Tangential Flow Filtration (TFF) steps including benzonase digestion.

BLA: 125678

Regulatory Milestone: No data available

PDUFA Goal Date: September 24, 2019

Package Insert: [Package Insert - JYNNEOS](#)

Summary Basis for Regulatory Approval: [September 24, 2019 Summary Basis for Regulatory Action - JYNNEOS](#)

European Public Assessment Report: None**Advisory Committee:**

This submission was not discussed at a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting because FDA review of this submission did not identify concerns or issues which would have benefitted from an advisory committee discussion.

Safety:

The safety profile of MVA-BN, including in HIV-infected subjects and subjects with AD, was favorable. The studies did not observe increased cardiac events among MVA-BN vaccinated individuals compared with placebo recipients. The submitted safety data also support use of MVA-BN in individuals infected with HIV or with AD.

NCT Numbers:

- NCT02977715

EudraCT Numbers: None**Publications:**

- Phelps, A., Gates, A. J., Eastaugh, L., Hillier, M., & Ulaeto, D. O. (2017). Comparative Efficacy of Intramuscular and Scarification Routes of Administration of Live Smallpox Vaccine in a Murine Challenge Model. *Vaccine*, 35(31), 3889–3896.
<https://doi.org/10.1016/j.vaccine.2017.05.058>
- Smallpox Vaccine. (2020). In *Drugs and Lactation Database (LactMed)*. National Library of Medicine (US).