BAVARIAN NORDIC

SMALLPOX

MVA-BN®

MVA-BN is approved in Canada (marketed under the trade name IMVAMUNE®) and in the European Union (marketed under the trade name IMVANEX®. Phase 3 registration trials have been successfully concluded in the U.S. and a BLA was filed with the FDA in October 2018.

MVA-BN is a non-replicating smallpox vaccine distributed in liquid-frozen formulation, suitable for use in people for whom replicating smallpox vaccines are contraindicated (e.g. people with HIV and atopic dermatitis). The vaccine is the only non-replicating smallpox vaccine approved in Europe for use in the general adult population. Although not yet approved in the United States, MVA-BN is currently stockpiled by the U.S. Government for emergency use in people for whom replicating smallpox vaccines are contraindicated. Registration studies to support FDA approval for use of the vaccine in the entire population have been concluded and a BLA was submitted in October 2018.

Traditional smallpox vaccines are based on replicating vaccinia virus strains. Although these vaccines have been effective in preventing the disease, their use may be associated with an increased risk of adverse events, including death and severe disability.

MVA-BN is injected like other modern vaccines rather than pricked into the skin with a bifurcated needle. While the MVA-BN virus is highly attenuated and is thus incapable of replicating in the body, it is still capable of eliciting a potent immune response and does so without producing the post-vaccination complications associated with traditional smallpox vaccines.

About smallpox