

Bavarian Nordic enters multiple smallpox vaccine contracts in response to monkeypox outbreak

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Danish vaccine company Bavarian Nordic has entered several new supply contracts with countries for its smallpox vaccine, with deliveries set to start immediately.

MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic is marketed as Jynneos in the US; Imvanex in Europe and Invamune in Canada. It is a non-replicating smallpox vaccine that was developed in collaboration with the US government to ensure a supply of smallpox vaccine.

The vaccine is the only one approved for use against monkeypox: with the indication granted by the US FDA and Health Canada (in Europe it is only approved for the smallpox indication but can be used off-label against monkeypox).

Company expects more orders

The new orders come on the back of a 'first larger vaccine contract' with an undisclosed government, which was announced last Wednesday (May 25).

Bavarian Nordic has not disclosed the countries involved in the new contracts nor the quantities and terms of agreements: stating only that 'a number of contracts of varying size have been signed'. As a consequence of these orders, however, it has raised its expectations for FY2022 with revenue now expected to be between DKK 1,400 and 1,600 million (previously between DKK 1,300 and 1,500 million),

"Bavarian Nordic is currently in dialogue with additional countries concerning supply of the vaccine to mitigate the current monkeypox outbreak and to explore opportunities for longer term collaboration to build stockpiles for future preparedness," said the company. *"In this unprecedented situation, the company is making every possible effort to ensure sufficient availability of vaccines to meet the current demand."*

Bavarian Nordic has ongoing supply contracts with USA and Canada and has delivered the vaccine to a number of undisclosed countries globally as part of their national biological preparedness against smallpox. In recent years, the vaccine has been supplied in response to sporadic cases of monkeypox.

The close relation of the responsible viruses means smallpox vaccines are effective against monkeypox. Jynneos is delivered as a 2 dose subcutaneous injection (day 0, day 28) - offering an advantage over smallpox vaccine ACAM2000 which [develops an infectious lesion](#).

Since May 13, monkeypox has been reported to WHO from 23 member states that are not endemic for monkeypox virus. The vast majority of reported cases so far have no established travel links to an endemic area, as had previously been the case for isolated cases in the past. As of Sunday (May 26), a total of 257 laboratory confirmed cases and around 120 suspected cases had been reported to the WHO: with the most confirmed cases in Portugal (49), Canada (26) and the US (10). No deaths have been reported.

Vaccine plant expansion

Vaccine doses are manufactured by Bavarian Nordic's own commercial-scale manufacturing facility in Kvistgaard, Denmark: which to date has manufactured 28 million doses of the smallpox vaccine to the U.S. Strategic National Stockpile.

Last year the company started an expansion of the facility with a commercial scale multi-product fill and finish facility for liquid and freeze-dried live viral vaccines, i.e. formulation, filling, freeze-drying, terminal sterilization of WFI (solvent for freeze-dried products), inspection and packaging. The first doses of a freeze-dried version of the vaccine with improved shelf-life are expected to be manufactured in 2023, with doses destined for the US under a \$119m option, the company announced on May 18.

In addition, a new clean room suite is being added to increase the capacity and flexibility of the existing multi-purpose manufacturing facility, by allowing multiple products to be manufactured in parallel.

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