



Bavarian Nordic

Bavarian Nordic A/S is a fully integrated biotechnology company focused on the development, manufacturing and commercialization of vaccines. The company is headquartered in Hellerup, Denmark, with manufacturing facilities in Kvistgård, Denmark and Thörishaus near Bern, Switzerland.^[3] The company has research and development facilities in Martinsried, Germany and San Diego, California, as well as offices in Zug, Switzerland, and Morrisville, North Carolina. The company uses viral vectors and virus-like particles in its research and development.

Technologies

MVA-BN

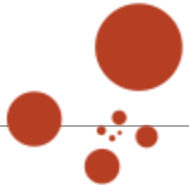
MVA-BN is a proprietary technology developed by Bavarian Nordic. It is derived from the Modified vaccinia Ankara virus. MVA-BN is characterized by the inability to replicate in human cells,^[7] contrary to other vaccinia-based vaccines, which may replicate in humans, thus potentially causing severe and life-threatening side effects. Developed as the non-replicating smallpox and monkeypox vaccine, MVA-BN is approved in Canada as Imvamune,^[8] in the European Union, as Imvanex,^[9] and the United States as Jynneos.^{[10][11][12]} The vaccine was supplied for emergency use to the U.S. Strategic National Stockpile as well as other government stockpiles.

The vaccine is being deployed worldwide to combat the 2022 monkeypox outbreak, leading to concerns over vaccine nationalism and hoarding by countries with pre-existing contracts.^[13]

Ebola vaccine development and production

The company has worked for several years with the NIAID^[14] on the development of a filovirus vaccine for Ebola and Marburg hemorrhagic fever diseases. In October 2014, following a successful pre-clinical demonstration of the combination vaccine

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 BAVARIAN NORDIC	
Company type	Public
Traded as	Nasdaq Copenhagen: BAVA (https://www.nasdaqomxnordic.com/shares/microsite?Instrument=CSE3333) OMXC25CAP component ^{[1][2]} OTC Markets: BVNRY (https://www.otcmarkets.com/stock/BVNRY/quote)
ISIN	DK0015998017 (https://isin.toolforge.org/?language=en&isin=DK0015998017)
Industry	Biotechnology
Founded	1994
Headquarters	Philip Heymans Alle 3 DK-2900 Hellerup, Hellerup ^[3] , Denmark
Key people	Luc Debryune (chairman) ^[4] Paul Chaplin (president and CEO) ^[5]

regimen of its multivalent MVA-BN Filovirus vaccine and Crucell/Janssen's AdVac technology based on adenoviral vectors, Bavarian Nordic joined efforts with Crucell Holland B.V., one of the Janssen Pharmaceuticals companies of Johnson & Johnson to develop and manufacture this vaccine regimen intended for emergency use to help contain the outbreak in West Africa.^{[15][16][17]} In January 2015, the company had produced the first 400,000 doses of the vaccine and the first clinical trial of the vaccine regimen was initiated in the UK, with additional trials planned in the US and Africa.^[18] It was approved for medical use in the European Union in July 2020.^[19]

Acquisitions

In October 2019, it was announced that Bavarian Nordic would acquire travel vaccines Rabipur(/Rabavert) for rabies and Encepur for tick-borne encephalitis (TBE) from GlaxoSmithKline (GSK).^{[20][21]} In February 2023, it was announced that Bavarian Nordic would acquire travel vaccines Vivotif for typhoid fever and Vaxchora for cholera, in addition to a late-stage candidate for chikungunya, from Emergent BioSolutions.^[22]

Marketed products and pipeline

Bavarian Nordic's marketed products and pipeline, as of July 2020.^{[23][24]}

Products	<u>Imvanex</u> , <u>Imvamune</u> , <u>Jynneos</u> , <u>Rabipur/RabAvert</u> , <u>Encepur</u> , <u>Vivotif</u> , <u>Vaxchora</u> , <u>Mvabea</u>
Revenue	▲ 7.062 billion kr. (2023)
Total assets	▲ 14.373 billion kr. (2023)
Total equity	▲ 10.340 billion kr. (2023)
Number of employees	▲ 1.379 (2023)
Website	<u>www.bavarian-nordic.com</u> (<u>https://www.bavarian-nordic.com</u>)
Footnotes / references ^[6]	

Product	Indication	Phase	Remark
<u>Imvanex</u>	Smallpox, monkeypox and disease caused by <u>vaccinia virus</u>	Approved EU 2013-07	Liquid-frozen.
<u>Imvamune</u>	<u>Smallpox</u>	Approved Canada 2013-11	Liquid-frozen.
<u>Jynneos</u>	<u>Smallpox and monkeypox</u>	Approved US 2019-09-24	Liquid-frozen.
MVA-BN (freeze-dried)	<u>Smallpox</u>	III	Phase 3 clinical trials completed.
Rabipur/RabAvert	(Pre-/post-exposure protection against) <u>rabies</u>	Approved	Acquisition completed on 31 December 2019. Bavarian Nordic assumes full sales and marketing responsibility from start 2020; manufacturing transfer takes place 2020-25 - during this period Bavarian Nordic will purchase remaining inventory of vaccines from GSK at different levels in the supply chain.
Encepur	European (Western) <u>tick-borne encephalitis (TBE) virus</u>	Approved	Acquisition completed on 31 December 2019. Bavarian Nordic assumes full sales and marketing responsibility from start 2020; manufacturing transfer takes place 2020-25 - during this period Bavarian Nordic will purchase remaining inventory of vaccines from GSK at different levels in the supply chain.
<u>Mvabea</u>	<u>Ebola and Marburg virus</u>	Approved EU 2020-07-01	Licensed to Janssen. One dose of Janssen's primer <u>Zabdeno®</u> (Ad26.ZEBOV) followed 8 weeks later by a dose of Bavarian Nordic's booster <u>Mvabea®</u> (MVA-BN Filo) collectively constitutes Janssen's Ebola vaccine regimen.
CHIKV VLP	<u>Chikungunya</u>	III	Ph3 topline results announced August 6, 2023. ^[25] Regulatory submissions planned for 2024. ^[26]
MVA-BN WEV	<u>Western equine encephalitis virus</u>	I	Ph1 topline results announced June 8, 2020. ^[27] A Phase 2 clinical study is planned for initiation in 2024. ^[28]


Associations

Bavarian Nordic is a member of the Medical Countermeasures Coalition, a group of companies, academic institutions, and other organizations dedicated to building an effective medical countermeasure enterprise through sound public policy and strong public-private partnerships.^[29]

The company is a funding partner of the Bipartisan Commission on Biodefense,^[30] and a former donor to the Bipartisan Policy Center.^[31]

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