

Bavarian Nordic

Helping to Protect Our Tomorrow With Vaccine Innovation

[Date]

[Speaker]

[Speaker Credentials]



Bavarian Nordic is a fully integrated vaccines company with a strong heritage in vaccine development with robust technologies and manufacturing capabilities

Covered by Bavarian Nordic

Covered by partners



WE ASPIRE TO BECOME ONE OF THE LARGEST PURE PLAY VACCINE COMPANIES BY 2025





Committed to Saving & Improving Lives



PIONEERING RESEARCH & DEVELOPMENT

Strong heritage in vaccine development and cutting-edge technology drives our innovation to fight existing and emerging diseases



EXPERTISE IN VACCINE MANUFACTURING

Expertise in live virus vaccine manufacturing and fill and finish capabilities enables our end-to-end commercial-scale manufacturing

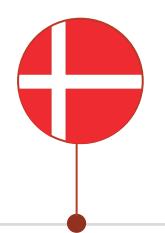


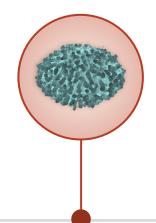
COMMERCIAL EXCELLENCE

Established commercial infrastructure with presence in key US and EU markets drives profitable growth of our expanding vaccine portfolio



Building on a Legacy of Vaccine Achievements

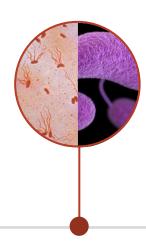












1994
Founded in Denmark

2007
First smallpox
supply contract with
US Government

2014
Entered collaboration
with Janssen for
development and supply
of Ebola vaccine

2019
Approval in the United States for Smallpox and Monkeypox Vaccine, Live, Nonreplicating suspension for subcutaneous injection

2020
US Commercial team established; acquisition of Rabies Vaccine

2023

Acquisition of Typhoid
Vaccine Live Oral Ty21a,
Cholera Vaccine Live Oral,
and a Phase 3 vaccine
candidate for the prevention
of Chikungunya virus from
Emergent BioSolutions



Rabies

BACKGROUND

Overview¹⁻³: Vaccine-preventable, viral disease that causes acute, progressive encephalomyelitis. As the virus moves to the CNS, progressive and fatal inflammation of the brain and spinal cord develop

Transmission¹: People are usually infected following a deep bite or scratch from an animal with rabies

Symptoms¹: Flu-like symptoms, pain, and unusual or unexplained tingling, pricking, or burning sensations at the wound site, which progresses to more severe symptoms, such as hallucinations, hydrophobia, paralysis, coma, and death

FAST FACTS

~99% of cases

worldwide are caused by transmission of the rabies virus via domestic dogs¹

BATS

are the major source of human rabies deaths in the Americas¹

40% of DEATHS

worldwide occur in children under 15 years of age¹

Nearly 100% FATAL

once clinical symptoms appear¹



Mpox (monkeypox)

BACKGROUND

Overview¹: Vaccine-preventable, viral infection that causes a painful rash, fever, and swollen lymph nodes

Transmission^{1,2}:

- Direct (person-to-person): Contact with infectious skin or other lesions, bodily fluids, respiratory secretions
- Direct (animal-to-human): Bites and scratches from or contact with infected animal
- Indirect (vehicle): Contaminated objects, such as bedding, clothing, or linens

Symptoms¹: Fever, rash, sore throat, headache, muscles aches, back pain, low energy, swollen lymph nodes

FAST FACTS

THE 2022 OUTBREAK

was caused by the Clade
IIb strain³

88,122 CASES

have been reported worldwide since 2022³

~35% OF CASES

have occurred in the United States since the outbreak began³

43 DEATHS

have been reported in the United States since 2022³



Typhoid Fever

BACKGROUND

Overview¹: Potentially severe and occasionally lifethreatening bacterial illness caused by *Salmonella* Typhi

Transmission - Indirect (vehicle)^{1,2}: Consumption of human feces contaminated food and water

Symptoms¹:

- Fever, headache, malaise, anorexia, constipation or diarrhea, fatigue, myalgias, and transient, maculopapular rash on the trunk
- Confusion, delirium, and intestinal perforation may occur in severe cases of typhoid fever, typically after 2 to 3 weeks of illness

FAST FACTS

TYPHOID FEVER REMAINS ENDEMIC IN

Asia, Africa, and Latin America¹ ~11-21
MILLION CASES

of typhoid fever occur worldwide each year¹

~135,000-230,000 DEATHS

are attributed to typhoid fever worldwide each year¹

~85% OF CASES

in the United States occur among international travelers¹



Cholera

BACKGROUND

Overview¹: Acute bacterial intestinal infection caused by toxigenic bacterium *Vibrio cholerae* serogroup O1 or O139

Transmission - Indirect (vehicle)^{1,2}: Most commonly via consumption of contaminated water; however, may also be acquired from eating contaminated raw or undercooked food, especially fish and shellfish

Symptoms^{1,3}:

- Cholera most commonly manifests as acute watery diarrhea
- Approximately 1 in 10 people with cholera will develop cholera gravis, a severe presentation characterized by profuse watery diarrhea and vomiting that can rapidly cause severe dehydration and death

FAST FACTS

Cholera is endemic in approximately
50 COUNTRIES³

~ 1.3-4.0

MILLION CASES

of cholera occur

worldwide each year⁴

UP TO 143,000 DEATHS

are attributed to cholera worldwide each year⁴

Cholera continues to be significantly underreported on a global scale, with only 5%-10% OF ACTUAL WORLDWIDE CASES REPORTED⁵



Bavarian Nordic

Establishing Global Leadership in Travel Health



Return to International Travel Amplifies the Need for Travel Health Vaccines



In December 2022, **17.6 million** US travelers flew to international destinations, representing **89% of the volume in December 2019**¹



COVID-19 created an unprecedented global awareness of vaccines and their role in helping to improve public health and helping to enable an open world



Travel health vaccines are seeing a rebound after the COVID-19 pandemic²



COVID-19, coronavirus disease 2019.

The Ongoing Need for Travel Health

- Travelers are likely to underestimate the risk of travelrelated illness¹
- Up to 79% of individuals visiting low- and middle-income countries will experience travel-associated illness and health issues²
- Travelers visiting friends and relatives (VFR) are at higher risk for travel-related illness due to longer visits at destinations with high disease endemicity and increased contact with contaminated food and water³



Pre-travel consultations
are important to educate
patients on reducing
health risks and
preventing infectious
disease through protective
behaviors and PrEP
medications and vaccines⁴

PrEP, pre-exposure prophylaxis.



1. Rossi IA, Genton B. *J Travel Med*. 2012;19(5):284-288. 2. CDC Yellow Book. Section 11. Posttravel Evaluation. General Approach to the Returned Traveler. Accessed July 12, 2023. https://wwwnc.cdc.gov/travel/yellowbook/2024/posttravel-evaluation/general-approach-to-the-returned-traveler 3. CDC Yellow Book. Section 9. Travel for Work & Other Reasons. Visiting Friends & Relatives: VFR Travel. Accessed July 12, 2023. https://wwwnc.cdc.gov/travel/yellowbook/2024/work-and-other-reasons/visiting-friends-and-relatives 4. CDC Yellow Book. Section 2. Preparing International Travelers. The Pretravel Consultation. Accessed July 12, 2023. https://wwwnc.cdc.gov/travel/yellowbook/2024/preparing/pretravel-consultation

An Evolving US Product Portfolio That Addresses Global Health Risks and Unmet Needs



RabAvert® (Rabies Vaccine)

RabAvert is indicated for pre-exposure vaccination, in both primary series and booster dose, and for post-exposure prophylaxis against rabies in all age group.



VIVOTIF® (Typhoid Vaccine Live Oral Ty21a)

VIVOTIF is indicated for immunization of adults and children greater than 6 years of age against disease caused by *Salmonella typhi*.



JYNNEOS® (Smallpox and Monkeypox Vaccine, Live, Non-Replicating)

JYNNEOS is approved for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox and monkeypox infection.



VAXCHORA® (Cholera Vaccine, Live, Oral)

VAXCHORA is a vaccine indicated for active immunization against disease caused by *Vibrio cholerae serogroup* O1 in persons 2 through 64 years of age traveling to cholera-affected areas.



Please see Indication and Important Safety Information for RabAvert on slides 14, 20-23, for JYNNEOS on slides 24-26, for VIVOTIF on slides 16-17, 27-28 and for VAXCHORA on slides 19, 29-31.

Please see full Prescribing Information for RabAvert, JYNNEOS, VIVOTIF, and VAXCHORA.

RabAvert® (Rabies Vaccine)

- RabAvert® is approved for pre-exposure vaccination and for post-exposure prophylaxis (PEP) against rabies in all age groups¹
- The safety and efficacy of RabAvert has been evaluated in more than 50 clinical trials²
- Following exposure, timely and appropriate PEP can help protect against rabies¹





NDC: 50632-010-01



Please see Indication and Important Safety Information for RabAvert on slide 14 and continued Important Safety Information on slides 20-23.

RabAvert® Indication and Important Safety Information

Indication

RabAvert is a vaccine approved for all age groups to help prevent rabies infection both before and after a suspected exposure.

Important Safety Information

People with a history of severe allergic reaction (e.g., anaphylaxis) to RabAvert or any of its ingredients should not receive RabAvert for protection before a potential exposure (PrEP) to the rabies virus. They should receive a different rabies vaccine if a suitable product is available. However, because rabies is almost always fatal if left untreated, the protection provided with RabAvert after a potential exposure (PEP) to the rabies virus outweighs the risks associated with a severe allergic reaction.

Please see continued Important Safety Information for RabAvert on slides 20-23.

Please see <u>full Prescribing Information for RabAvert</u>.



VIVOTIF® (Typhoid Vaccine Live Oral Ty21a)

- VIVOTIF® is approved for the prevention of typhoid fever in persons aged 6 years and older
- Since its approval in 1989, more than 150 million doses of VIVOTIF have been marketed worldwide
- Not all recipients of VIVOTIF will be fully protected against typhoid fever. Vaccinated individuals should continue to take personal precautions against exposure to typhoid organisms.





Please see Indication and Important Safety Information for VIVOTIF on slides 16-17 and continued Important Safety Information on slides 27-28.

VIVOTIF® Indication

Indication and Usage

VIVOTIF is indicated for immunization of adults and children greater than 6 years of age against disease caused by Salmonella typhi.

Routine typhoid vaccination is not recommended in the United States of America. Selective immunization against typhoid fever is recommended for the following groups: 1) travelers to areas in which there is a recognized risk of exposure to S. Typhi; 2) persons with intimate exposure (e.g., household contact) to an S. Typhi carrier; and 3) microbiology laboratorians who work frequently with S. Typhi. There is no evidence to support the use of typhoid vaccine to control common source outbreaks, disease following natural disasters, or in persons attending rural summer camps.

Not all recipients of VIVOTIF will be fully protected against typhoid fever. Vaccinated individuals should continue to take personal precautions against exposure to typhoid organisms.

Please see continued Indication and Usage for VIVOTIF on slide 17, Important Safety Information on slide 17, and continued Important Safety Information on slides 27-28.



VIVOTIF Indication and Important Safety Information

Important Safety Information (cont.)

The vaccine will not afford protection against species of Salmonella other than Salmonella Typhi or other bacteria that cause enteric disease. The vaccine is not suitable for treatment of acute infections with S. Typhi.

Important Safety Information

VIVOTIF is contraindicated in patients with a hypersensitivity to any component of the vaccine or the enteric-coated capsule. The vaccine should not be administered to persons during an acute febrile illness. Safety of the vaccine has not been demonstrated in persons deficient in their ability to mount a humoral or cell-mediated immune response, due to either a congenital or acquired immunodeficient state including treatment with immunosuppressive or antimitotic drugs. The vaccine should not be administered to these persons regardless of benefits.

Please see continued Important Safety Information for VIVOTIF on slides 27-28.

Please see <u>full Prescribing Information for VIVOTIF</u>.



VAXCHORA® (Cholera Vaccine, Live, Oral)

- VAXCHORA® is a cholera vaccine indicated for use in travelers 2-64 years of age
- VAXCHORA is contraindicated in persons who have a history of severe allergic reaction (e.g., anaphylaxis) to any ingredient of VAXCHORA or to a previous dose of any cholera vaccine.







Please see Indication and Important Safety Information for VAXCHORA on slide 19 and continued Important Safety Information on slides 29-31.

VAXCHORA® Indication and Important Safety Information

Indication and Usage

VAXCHORA is a vaccine indicated for active immunization against disease caused by *Vibrio cholerae* serogroup O1 in persons 2 through 64 years of age traveling to cholera-affected areas.

Limitations of Use: The effectiveness of VAXCHORA has not been established in persons living in cholera-affected areas. The effectiveness of VAXCHORA has not been established in persons who have pre-existing immunity due to previous exposure to V. cholerae or receipt of a cholera vaccine. VAXCHORA has not been shown to protect against disease caused by V. cholerae serogroup O139 or other non-O1 serogroups.

Important Safety Information

VAXCHORA is contraindicated in persons who have a history of severe allergic reaction (e.g., anaphylaxis) to any ingredient of VAXCHORA or to a previous dose of any cholera vaccine.

Please see continued Important Safety Information for VAXCHORA on slides 29-31.

Please see <u>full Prescribing Information for VAXCHORA</u>.



The ingredients of RabAvert, which could in rare cases, cause allergic reactions in some people, include egg and chicken proteins, processed bovine (cow) gelatin and trace amounts of neomycin, chlortetracycline, and amphotericin B. Let your healthcare professional know if you have had any issues, including allergic reactions, with any of these ingredients or with vaccines in general.

Severe, potentially life-threatening allergic reaction, swelling of the brain and spinal cord; loss of movement or sensation due to nerve damage, such as inflammation of the brain or temporary loss of movement; Guillain-Barré Syndrome; inflammation of spinal cord; inflamed nerves of the eye; and multiple sclerosis have in very rare cases been reported.

RabAvert should be injected into muscle only. RabAvert injected into a vein may cause a reaction throughout the body, including shock.

Fainting can occur when injectable vaccines are used, including RabAvert. Your healthcare provider should put procedures in place to avoid falling injury and to restore blood flow to the brain after fainting.

Please see continued Important Safety Information for RabAvert on slides 21-23.



Patients with a weakened immune system due to illness or the use of certain medications or treatments (such as radiation therapy, antimalarials, and corticosteroids) may have issues developing immunity. If such a patient is receiving RabAvert, then the healthcare professional may measure immune response through blood testing. Vaccination with RabAvert for protection before a potential exposure (PrEP) to the rabies virus should be delayed in anyone who is sick or recovering from an illness.

RabAvert contains albumin which is a protein found in human blood that carries an extremely remote risk for transmission of viral diseases, including Creutzfeldt-Jakob disease (CJD), a rare brain disorder. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

Persons who have not been previously vaccinated against rabies will receive Human Rabies Immune Globulin (HRIG). HRIG should not be administered to persons who have been previously vaccinated as it may counteract the effect of the rabies vaccine. Let your healthcare provider know if you were previously vaccinated for rabies as you may not need HRIG.

Please see continued Important Safety Information for RabAvert on slides 22-23.



Only use RabAvert while pregnant or breastfeeding if clearly needed. RabAvert was not studied in pregnant or lactating women so it is not known if RabAvert can cause any harm to the fetus, have any effect on ability to get pregnant, or whether it is passed through breast milk to infants (but many drugs are excreted in human milk).

There is no information on how RabAvert works when given at the same time as other vaccines.

The most common side effects in clinical trials were reactions at the injection site, such as reddening, hardening, and pain; flu-like symptoms, such as lack of energy, tiredness, fever, headache, muscle pain, and feeling of discomfort; joint pain; dizziness; swelling of lymph nodes; upset stomach; and rash.

Vaccination before a potential exposure (PrEP) to the rabies virus does not remove the need for additional therapy after a suspected or known rabies exposure.

Please see continued Important Safety Information for RabAvert on slide 23.



Seek the advice of a healthcare professional to help assess your specific level of risk if you are traveling to areas of high risk of rabies exposure; in frequent contact with the rabies virus or rabid animals, such as on the job; and/or are active outdoors and could encounter animals with rabies in the wild.

If you are exposed to a potentially rabid animal, seek medical attention right away before you have symptoms. Once symptoms are present, the rabies infection has spread through the body and survival is unlikely.

Uses for RabAvert

RabAvert is a vaccine approved for all age groups to help prevent rabies infection both before and after a suspected exposure.

Patients should always ask their healthcare professionals for medical advice about the appropriate use of vaccines and adverse events. To report SUSPECTED ADVERSE REACTIONS, contact Bavarian Nordic at 1-844-4BAVARIAN or the US Department of Health and Human Services by either visiting www.vaers.hhs.gov/reportevent.html or calling 1-800-822-7967.

Please see <u>full Prescribing Information</u>



JYNNEOS® Indication and Important Safety Information

Indication

JYNNEOS is approved for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox and monkeypox infection.

Important Safety Information

Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of JYNNEOS. Anyone who has who experienced a severe allergic reaction following a previous dose of JYNNEOS or following exposure to any component of JYNNEOS may be at increased risk for severe allergic reactions.

Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.

Vaccination with JYNNEOS may not protect all recipients.

Please see continued Important Safety Information for JYNNEOS on slides 25-26.



JYNNEOS Important Safety Information (cont.)

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 (firmness at the injection site) (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%).

The frequencies of solicited local and systemic adverse reactions among adults with HIV infection and adults with atopic dermatitis were generally similar to those observed in healthy adults.

Across all studies, a causal relationship to JYNNEOS could not be excluded for 4 SAEs, all non-fatal, which included Crohn's disease, sarcoidosis, extraocular muscle paresis and throat tightness.

Please see continued Important Safety Information for JYNNEOS on slide 26.



JYNNEOS Important Safety Information (cont.)

Cardiac adverse events of special interest (AESIs) considered causally related to study vaccination were reported in 0.08% of subjects who received JYNNEOS and included tachycardia, electrocardiogram T wave inversion, electrocardiogram abnormal, electrocardiogram ST segment elevation, electrocardiogram T wave abnormal, and palpitations. None of the cardiac AESIs considered causally related to study vaccination were considered serious.

To report SUSPECTED ADVERSE REACTIONS, contact Bavarian Nordic at 1-844-4BAVARIAN or the US Department of Health and Human Services by either visiting www.vaers.hhs.gov/reportevent.html or calling 1-800-822-7967.

Please see full Prescribing Information



VIVOTIF Important Safety Information (cont.)

Acute Gastrointestinal Illness: VIVOTIF is not to be taken during an acute gastrointestinal illness. Postpone taking the vaccine if persistent diarrhea or vomiting occurs.

Concomitant Administration with Sulfonamides and Antibiotics: The vaccine should not be administered to individuals receiving sulfonamides and antibiotics since these agents may be active against the vaccine strain and prevent a sufficient degree of multiplication to occur in order to induce a protective immune response.

Diminished Immune Response: Unless a complete immunization schedule is followed, an optimum immune response may not be achieved. Not all recipients of VIVOTIF will be fully protected against typhoid fever.

Personal Precautions: Vaccinated individuals should continue to take personal precautions against exposure to typhoid organisms (i.e., travelers should take all necessary precautions to avoid contact or ingestion of potentially contaminated food or water).

Please see continued Important Safety Information for VIVOTIF on slide 28.



VIVOTIF Important Safety Information (cont.)

Concomitant Administration with Anti-malarial Drugs: Several anti-malaria drugs, such as mefloquine, chloroquine and proguanil (not approved for use in US) possess anti-bacterial activity which may interfere with the immunogenicity of VIVOTIF. A study showed that mefloquine and chloroquine can be administered together with VIVOTIF. Proguanil should be administered only if 10 days or more have elapsed since the final dose of VIVOTIF was ingested.

Adverse Reactions: The most common adverse reactions in clinical trials were abdominal pain (6.4%), nausea (5.8%), headache (4.8%), fever (3.3%), diarrhea (2.9%), vomiting (1.5%) and skin rash (1.0%). Only the incidence of nausea occurred at a statistically higher frequency in the vaccinated group as compared to the placebo group.

Please see <u>full Prescribing Information</u>



VAXCHORA Important Safety Information (cont.)

<u>Altered Immunocompetence:</u> The safety and effectiveness of VAXCHORA have not been established in immunocompromised persons and the immunologic response to VAXCHORA may be diminished in immunocompromised individuals.

<u>Shedding and Transmission:</u> Because VAXCHORA may be shed in the stool of recipients for at least 7 days and the vaccine strain can potentially be transmitted to non-vaccinated close contacts (e.g., household contacts), use caution when considering whether to administer VAXCHORA to individuals with immunocompromised close contacts.

Please see continued Important Safety Information for VAXCHORA on slides 30-31.



VAXCHORA Important Safety Information (cont.)

Adverse Reactions: In adults 18-45 years old, the most common adverse reactions (incidence > 3%) were tiredness (31%), headache (29%), abdominal pain (19%), nausea/vomiting (18%), lack of appetite (17%) and diarrhea (4%).

The most common adverse reactions for children and adolescents (incidence ≥10%) were:

- Cohort 1 age 12-<18 years: headache (45%), tiredness (41%), abdominal pain (38%), lack of appetite (29%) and nausea (22%)
- Cohort 2 age 6-<12: tiredness (35%), abdominal pain (27%), headache (26%), lack of appetite (15%) and nausea (14%)
- Cohort 3 age 2-<6: tiredness (31%), lack of appetite (19%), and abdominal pain (17%)

Please see continued Important Safety Information for VAXCHORA on slide 31.



VAXCHORA Important Safety Information (cont.)

<u>Antibiotics:</u> Avoid concomitant administration of VAXCHORA with oral systemic antibiotics since these agents may be active against the vaccine strain. Do not administer VAXCHORA to patients who have received oral or parenteral antibiotics within 14 days prior to vaccination.

<u>Antimalarial Prophylaxis:</u> Immune responses to VAXCHORA may be diminished when administered concomitantly with chloroquine. Administer VAXCHORA at least 10 days before beginning chloroquine.

<u>Immunosuppressive Treatments:</u> Immunosuppressive therapies may reduce the immune response to VAXCHORA.

Please see <u>full Prescribing Information</u>



Distributor Partners

Contact an authorized wholesaler or distributor to order RabAvert, VIVOTIF and VAXCHORA:

AmerisourceBergen: (844) 222-2273

Anda*: (800) 647-0575

ASD: (800) 746-6273

Besse Medical: (800) 543-2111

Cardinal Health: (800) 926-3161

DMS Pharmaceutical*: (877) 788-1100

Henry Schein*: (800) 472-4346

McKesson (Hospitals and health systems): (855) 625-4677

McKesson (Independent pharmacies): (855) 625-7385

McKesson (Medical-Surgical): (855) 571-2100

McKesson (National chain pharmacies): (855) 625-6285

Medico-Mart: (800) 242-6248

Morris & Dickson Specialty Division*: (800) 388-3833

R&S Pharmaceutical*: (800) 262-7770



^{*}RabAvert distributor only. VIVOTIF and VAXCHORA are not available to order.

For More Information, Contact:

Customer Service:

[USSupport@Bavarian-Nordic.com] or [1-844-4BAVARIAN (422827426)]

Medical Information Request:

[medical.information_us@bavarian-nordic.com] or [1-844-4BAVARIAN (422827426)]

For General Information: www.bavarian-nordic.com

Reporting Suspected Side Effects: [drug.safety@bavarian-nordic.com]

Reporting any deviation of the pharmaceutical properties listed in the package insert or summary of product characteristics (Product Quality Complaints): [quality.complaints@bavarian-nordic.com]





