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# Merck Announces FDA Approval for ERVEBO® (Ebola Zaire Vaccine, Live)

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## Terms:

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## Dateline City:

KENILWORTH, N.J.

## *Action Represents Another Milestone for the Global Partnership Against Ebola*

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved ERVEBO® (Ebola Zaire Vaccine, Live) (pronounced er-VEE-boh) for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older. The duration of protection conferred by ERVEBO is unknown. ERVEBO does not protect against other species of *Ebolavirus* or *Marburgvirus*. Effectiveness of the vaccine when administered concurrently with antiviral medication, immune globulin (IG), and/or blood or plasma transfusions is unknown. Do not administer ERVEBO to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including rice protein.

"Approval of this vaccine by the FDA represents another important milestone in the global response to Ebola Virus Disease and stands as a tremendous accomplishment by a unique global partnership," said Dr. Roger M. Perlmutter president, Merck Research Laboratories. "In acknowledging this event, I wish in particular to recognize the heroic efforts being made by frontline responders to the ongoing outbreak in the Democratic Republic of the Congo. We are proud and honored to play a role in supporting their vital activities, and we remain focused on the important work ahead."

"Having an Ebola vaccine approved by the FDA is a significant milestone in Ebola preparedness and prevention efforts," said Rick Bright, Ph.D., deputy assistant secretary for preparedness and response and director of the Biomedical Advanced Research and Development Authority (BARDA). "At BARDA, we are tremendously proud to have been a part of this unprecedented collaboration between private and public sectors in multiple countries that has led to this important moment in public health history."

As previously announced, Merck is working to initiate manufacturing of licensed doses and expects these doses to start becoming available in approximately the third quarter of 2020. Merck is working closely with the U.S. government, WHO, UNICEF, and Gavi (the Vaccine Alliance) to plan for how eventual, licensed doses will support future public health preparedness and response efforts against *Zaire ebolavirus* disease.

During this transition period, Merck continues to work urgently with its partners to ensure uninterrupted access to the investigational Ebola Zaire vaccine (V920) in support of ongoing international response efforts in the Democratic Republic of the Congo and neighboring countries. Merck has, to date, shipped more than 275,000 1.0mL doses of V920 based on requests by the WHO.

Merck has also made submissions to African country national regulatory authorities in collaboration with the African Vaccine Regulatory Forum (AVAREF), that will allow the vaccine to be registered in African countries considered to be at-risk for Ebola outbreaks by the WHO.

## Selected Safety Information for ERVEBO

### CONTRAINDICATIONS

Do not administer ERVEBO to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including rice protein.

### WARNINGS AND PRECAUTIONS

#### Management of Acute Allergic Reactions

Among 15,399 subjects vaccinated with ERVEBO, there were two reports of anaphylaxis. Monitor individuals for signs and symptoms of hypersensitivity reactions following vaccination with ERVEBO. Appropriate medical treatment and supervision must be available in case of an anaphylactic event following the administration of ERVEBO.

#### Limitations of Vaccine Effectiveness

Vaccination with ERVEBO may not protect all individuals. Vaccinated individuals should continue to adhere to infection control practices to prevent *Zaire ebolavirus* infection and transmission.

### **Immunocompromised Individuals**

The safety and effectiveness of ERVEBO have not been assessed in immunocompromised individuals. The effectiveness of ERVEBO in immunocompromised individuals may be diminished. The risk of vaccination with ERVEBO, a live virus vaccine, in immunocompromised individuals should be weighed against the risk of disease due to *Zaire ebolavirus*.

### **Transmission**

Vaccine virus RNA has been detected by RT-PCR in blood, saliva, urine, and fluid from skin vesicles of vaccinated adults. Transmission of vaccine virus is a theoretical possibility.

### **ADVERSE REACTIONS**

The clinical development program for ERVEBO included clinical studies conducted in North America, Europe and Africa, in which a total of 15,399 adults received a dose of ERVEBO. The total number of subjects vaccinated with ERVEBO in double-blind, placebo-controlled trials was 1,712 and in open label trials was 13,687.

The most common injection-site adverse reactions reported by subjects taking ERVEBO in Study 1 (N=500) were injection-site pain (34.0%) and redness/swelling (2%). The most common injection-site adverse reactions reported by subjects taking ERVEBO in Study 2 (N=1051) were injection-site pain (70.0%), swelling (17%), and redness (12%).

The most common systemic adverse reactions reported following vaccination with ERVEBO in Study 1 (N=498) were headache (37%), feverishness (34%), muscle pain (33%), fatigue (19%), nausea (8%), joint pain/tenderness (7%), rash (4%), and abnormal sweating (3%). The most common systemic adverse reactions reported following vaccination with ERVEBO in Study 2 (N=1051) were joint pain (18%), arthritis (5%), rash (4%), and vesicular lesions (2%).

Arthralgia was reported to occur in 7% to 40% of vaccine recipients in blinded, placebo-controlled studies. Severe arthralgia, defined as preventing daily activity, was reported in up to 3% of subjects.

Arthritis (including events of arthritis, joint effusion, joint swelling, osteoarthritis, monoarthritis or polyarthritis) was reported to occur in 0% to 24% of subjects in blinded, placebo-controlled studies in which subjects received ERVEBO or a lower dose formulation, with all but one study reporting arthritis in <5% of subjects. Most occurrences of arthritis were reported within the first few weeks following vaccination, were of mild to moderate intensity, and resolved within several weeks after onset. In one study conducted in Switzerland (Study 5, NCT02287480), 102 subjects received ERVEBO or a lower dose formulation. In this study, arthritis was reported to occur in 24% of subjects and severe arthritis, defined as preventing daily activity, in 12% of subjects.

Rash was reported to occur after administration of ERVEBO in blinded, placebo-controlled studies, with all but one study reporting rash in <9% of subjects. In Study 5, rash was reported to occur in 25% (n=4) of ERVEBO recipients and 7.7% (n=1) of placebo recipients.

White blood cell counts were assessed in 697 subjects who received ERVEBO. Decreases in lymphocytes were reported in up to 85% of subjects and decreases in neutrophils were reported in up to 43% of subjects. No associated infections were reported.

Among 15,399 ERVEBO recipients, two serious adverse reactions of pyrexia were reported as vaccine-related. In addition, two serious adverse reactions of anaphylaxis were reported as vaccine-related. None of these serious adverse reactions were fatal.

### **DRUG INTERACTIONS**

#### **Interference with Laboratory Tests**

Following vaccination with ERVEBO, individuals may test positive for anti-Ebola glycoprotein (GP) antibody and/or Ebola GP nucleic acid or antigens. GP-based testing may have limited diagnostic value during the period of vaccine viremia, in the presence of vaccine-derived Ebola GP, and following antibody response to the vaccine.

### **USE IN SPECIFIC POPULATIONS**

#### **Pregnancy**

There are no adequate and well-controlled studies of ERVEBO in pregnant women, and human data available from clinical trials with ERVEBO are insufficient to establish the presence or absence of vaccine-associated risk during pregnancy.

The decision to vaccinate a woman who is pregnant should consider the woman's risk of exposure to *Zaire ebolavirus*.

#### **Lactation**

Human data are not available to assess the impact of ERVEBO on milk production, its presence in breast milk, or its effects on the breastfed child. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ERVEBO and any potential adverse effects on the breastfed child from ERVEBO or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by the vaccine.

#### **Geriatric Use**

Clinical studies of ERVEBO did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger subjects.

## More About the Development of the Vaccine

ERVEBO, known as V920 in its investigational phase, was initially engineered by scientists from the Public Health Agency of Canada's National Microbiology Laboratory and the technology was subsequently licensed by a subsidiary of NewLink Genetics Corporation. In late 2014, when the Ebola outbreak in western Africa was at its peak, and with the goal of applying its capabilities in process research, clinical development, and manufacturing to an important global effort, Merck acquired the rights to develop V920 from NewLink Genetics. Since that time, the company has worked closely with a diverse range of external collaborators to enable a broad clinical development program with partial funding from the U.S. government, including the Department of Health and Human Service's Biomedical Advanced Research Development Authority (BARDA) and the Department of Defense's Defense Threat Reduction Program (DTRA) and Joint Vaccination Acquisition Program (JVAP). Beginning in 2015 Merck began manufacturing the emergency-use supplies that have been used to support outbreak response efforts prior to availability of licensed doses in collaboration with Gavi. Merck's ongoing V920 vaccine supply replenishment activities are supported by partial Federal funding from BARDA under Contract No. HHSO100201700012C. Merck has been responsible for the research, development, manufacturing and regulatory efforts in support of V920. The company has committed to working closely with other stakeholders to accelerate the continued development, production and availability of the vaccine.

## About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on [Twitter](#), [Facebook](#), [Instagram](#), [YouTube](#) and [LinkedIn](#).

## Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2018 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

Before administering ERVEBO® (Ebola Zaire Vaccine, Live), please read the [Prescribing Information at https://www.merck.com/product/usa/pi\\_circulars/e/ervebo/ervebo\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/e/ervebo/ervebo_pi.pdf). The [Patient Information](https://www.merck.com/product/usa/pi_circulars/e/ervebo/ervebo_ppi.pdf) is also available at [https://www.merck.com/product/usa/pi\\_circulars/e/ervebo/ervebo\\_ppi.pdf](https://www.merck.com/product/usa/pi_circulars/e/ervebo/ervebo_ppi.pdf).

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