



NEWS RELEASE

Merck Confirms Agreement with UNICEF to Establish the World's First Global Ebola Vaccine Stockpile with ERVEBO® (Ebola Zaire Vaccine, Live)

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Milestone represents another landmark moment in the global fight against Ebola virus disease thanks to science, innovation and global collaboration

KENILWORTH, N.J. January 13, 2021 -- Merck (NYSE:MRK), known as MSD outside the United States and Canada, today confirmed an agreement with UNICEF to establish the world's first global Ebola vaccine stockpile with ERVEBO® (Ebola Zaire Vaccine, Live). This agreement represents another landmark milestone in the fight against Ebola and is the result of breakthrough innovation and collaboration across Africa and the world. ERVEBO is a vaccine indicated 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 severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including rice protein.

The global stockpile will offer a critical, rapid-response tool to help combat future outbreaks of this highly contagious, hemorrhagic illness that is endemic in parts of Central and West Africa. The stockpile inventory will be built over time and maintained by Merck. To ensure equitable and public health risk-based use of the vaccine, the stockpile will be governed by the International Coordinating Group (ICG) on Vaccine Provision in accordance with guidance from the Strategic Advisory Group of Experts (SAGE) on immunization. Any country in the world will be eligible to request vaccine from ICG should it face an imminent risk or relevant need. ICG members include the World Health Organization (WHO), UNICEF, Médecins Sans Frontières (MSF), and the International Federation of Red

Cross and Red Crescent Societies (IFRC). Gavi, the Vaccine Alliance, as a key collaborator of the ICG, is financing the stockpile and funding the deployment of vaccines for Gavi eligible countries.

John Markels, PhD, President of Merck Vaccines, said, “For Merck, bringing forward medicines and vaccines to fight infectious diseases is fundamental to our mission to save and improve lives around the world. It has been our honor to collaborate with WHO, Gavi, UNICEF, the United States government and many others in getting to this point. While there remains important work ahead, the stockpile is a new and powerful tool in supporting future outbreak preparedness and response efforts. This historic milestone demonstrates what’s possible when partners come together to pursue a common purpose.”

Merck’s agreement with UNICEF represents the company’s commitment to global, equitable, and sustainable access to all our medicines and vaccines. Given the unique nature of Ebola virus disease and what is relatively low demand for ERVEBO compared to routine vaccines, we are only seeking to recover manufacturing and operational costs associated with the program and charging what it costs to make and manage the vaccine.

Merck believes that the recent Ebola outbreaks in the Democratic Republic of the Congo present an urgent call to action for the world. Sustained attention and investment in health security, including a robust market for innovation and continued collaboration are essential to be better prepared to address future infectious disease threats.

More Information on ERVEBO

ERVEBO 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 now known as Lumos Pharma, Inc. ERVEBO was conditionally approved by the European Medicines Agency on November 11, 2019, obtained pre-qualification from the World Health Organization on November 12, 2019, was then approved by the U.S. Food and Drug Administration on December 20, 2019 and is now registered for use in 8 African countries. Since the outbreak began in the Democratic Republic of the Congo in 2018, Merck has donated more than 305,000 1.0 mL investigational doses of the vaccine to the response efforts under the auspices of an Expanded Access protocol.

Selected Safety Information for ERVEBO

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 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 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%). Study 1 was conducted in Liberia (N=1,000). Subjects were randomized 1:1 to receive ERVEBO or saline placebo and were assessed at Week 1 and Month 1 postvaccination for solicited local and systemic reactions. In a subset of subjects (n=201), joint symptoms and signs were also solicited during a Week 2 visit.

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 2 (N=1051) were joint pain (18%), arthritis (5%), rash (4%), and vesicular lesions (2%). Study 2 was conducted in the United States, Canada, and Spain (N=1,197). Subjects were randomized to receive ERVEBO (n=1,061) or saline placebo (n=133). Subjects recorded solicited local reactions from

Days 1 to 5 postvaccination, and daily temperature measurements and solicited joint and skin events from Days 1 to 42 postvaccination.

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

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.

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.

About Merck

For more than 125 years, Merck, 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 in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit 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. 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 the global outbreak of novel coronavirus disease (COVID-19); 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 2019 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)

Before administering ERVEBO® (Ebola Zaire Vaccine, Live), please read the [Prescribing Information](https://www.merck.com/product/usa/pi_circulars/e/ervebo/ervebo_pi.pdf) at 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

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