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U.S. FDA Approves Merck's ERVEBO® (Ebola Zaire Vaccine, Live) for Use in Children 12 Months of Age and Older

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Merck continues progress in helping to protect people at risk of *Zaire ebolavirus* disease

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for ERVEBO, which is now indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 12 months of age and older. The vaccine was previously approved for use in individuals 18 years of age and older. ERVEBO does not protect against other species of *Ebolavirus* or *Marburgvirus* and the duration of protection conferred by ERVEBO is unknown. The effectiveness of the vaccine when administered concurrently with antiviral medication, immune globulin (IG), and/or blood or plasma transfusions is unknown. ERVEBO includes a contraindication for individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including rice protein.

"Ebola virus disease is contagious and potentially deadly in both children and adults. We're proud of the approval of ERVEBO for the prevention of disease caused by *Zaire ebolavirus* in children as young as 12 months old, which is another milestone in our continued commitment to help address the global health threat caused by *Zaire ebolavirus*," said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories.

Separately, on July 20, 2023, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended the expanded approval of ERVEBO® [Ebola Zaire Vaccine, (rVSVΔG-ZEBOV-GP) live], for active immunization of individuals 1 year of age or older to protect against Ebola Virus Disease (EVD) caused by *Zaire ebolavirus*. ERVEBO is currently authorized for use in the European Union (EU) for individuals 18 years of age and older. The CHMP opinion will now be considered by the European Commission for amending the marketing

authorization, and a final decision is expected in the third quarter of 2023.

In January 2021, Merck confirmed an agreement with UNICEF to establish the world's first global Ebola vaccine stockpile with ERVEBO to support future *Zaire ebolavirus* outbreak preparedness and response efforts. As of March 2023, over 500,000 doses of the licensed vaccine have been delivered to the stockpile, which is administered by the International Coordinating Group on Vaccine Provision.

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 18,616 participants vaccinated with at least one dose of ERVEBO in clinical trials, 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 individuals. Transmission of vaccine virus is a theoretical possibility.

ADVERSE REACTIONS
The most commonly reported local and systemic adverse events in clinical trials were:

— Individuals 18 years of age and older: injection-site pain (70%); headache (55%); feverishness (39%); muscle pain (33%); somnolence, reduced activity, fatigue (26%); joint pain, arthralgia (19%); chills (17%); injection-site swelling (17%); decreased appetite (15%); abdominal pain (13%); injection-site redness (12%); nausea (10%); arthritis (5%); vomiting (4%), rash (4%);

abnormal sweating (3%) and mouth ulceration (2%).

- Individuals 12 months through 2 years of age: feverishness (83%); crying (31%); decreased appetite (27%); injection-site pain (26%); somnolence, reduced activity, fatigue (20%); diarrhea (19%); vomiting (17%); irritability (11%); screaming (10%); mouth ulceration (6%); chills (5%); injection-site swelling (5%); headache (4%); abdominal pain (2%); abnormal sweating (2%) and injection-site erythema (1%).
- Individuals 3 years through 11 years of age: feverishness (65%); headache (50%); injection-site pain (40%); decreased appetite (24%); somnolence, reduced activity, fatigue (22%); abdominal pain (21%); chills (14%); myalgia (12%); vomiting (11%); dizziness (8%); nausea (8%); injection-site pruritus (7%); crying (3%); arthralgia (3%); diarrhea (3%); injection-site swelling (3%); abnormal sweating (1%); mouth ulceration (2%) and irritability (1%).
- Individuals 12 years through 17 years of age: headache (59%); injection-site pain (52%); feverishness (48%); myalgia (30%); somnolence, reduced activity, fatigue (28%); decreased appetite (21%); chills (19%); dizziness (17%); abdominal pain (16%); arthralgia (16%); nausea (8%); abnormal sweating (5%); diarrhea (4%); vomiting (4%); injection-site pruritus (3%); injection-site swelling (3%) and mouth ulceration (2%).

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.

INDICATIONS AND USAGE

ERVEBO® is indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 12 months of age and older.

Limitations Of Use

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.

About Ebola Virus Disease

Ebola virus disease is a rapidly progressive, severe, potentially fatal and transmissible hemorrhagic illness caused by infection with one of the Ebola virus species. While there are six identified Ebola virus species, the *Zaire ebolavirus* strain has been the leading cause of outbreaks over the last 20 years. The average fatality rate for Ebola virus disease is approximately 50% but has ranged from 25% to 90% in previous outbreaks.

Human-to-human transmission can occur via blood or bodily fluids, objects (like needles and syringes), possibly from contact with semen from a man who has recovered from Ebola, or direct contact through broken skin or mucous membranes.

About ERVEBO ® (Ebola Zaire Vaccine, Live) Suspension for intramuscular injection

ERVEBO® is indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 12 months of age and older. ERVEBO is a live recombinant viral vaccine consisting of a vesicular stomatitis virus (VSV) backbone deleted for the VSV envelope glycoprotein and substituted with the envelope glycoprotein of the *Zaire ebolavirus* (Kikwit 1995 strain).

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. Merck licensed the vaccine in 2014 and led research and development efforts in collaboration with a number of public health organizations to enable a broad clinical development program. This project has been funded in part with federal funds from the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201700012C.

The National Institute of Allergy and Infectious Diseases (NIAID), L'institut National de la Santé et de la Recherche Médicale (INSERM), and the London School of Hygiene and Tropical Medicine (LSHTM) sponsored the PREVAC study, designed to evaluate the safety and immunogenicity of two Ebola virus disease vaccine candidates, including ERVEBO, in adults and children aged 12 months and older.

ERVEBO is approved in the European Union, United Kingdom, United States, Canada, Switzerland, and 10 countries in Africa.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in

people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. 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., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, 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 candidates that the candidates 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 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 Annual Report on Form 10-K for the year ended December 31, 2022 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

Please see Prescribing Information for ERVEBO at https://www.merck.com/product/usa/pi_circulars/e/ervebo/ervebo_pi.pdf and Patient Information for ERVEBO at https://www.merck.com/product/usa/pi_circulars/e/ervebo/ervebo_ppi.pdf.

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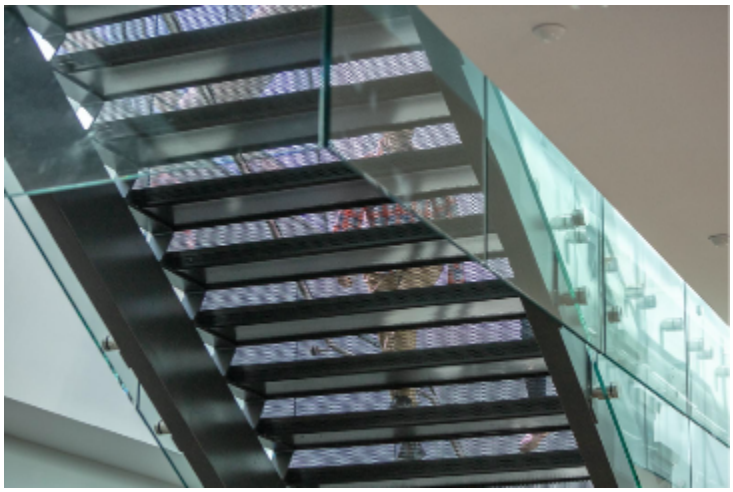

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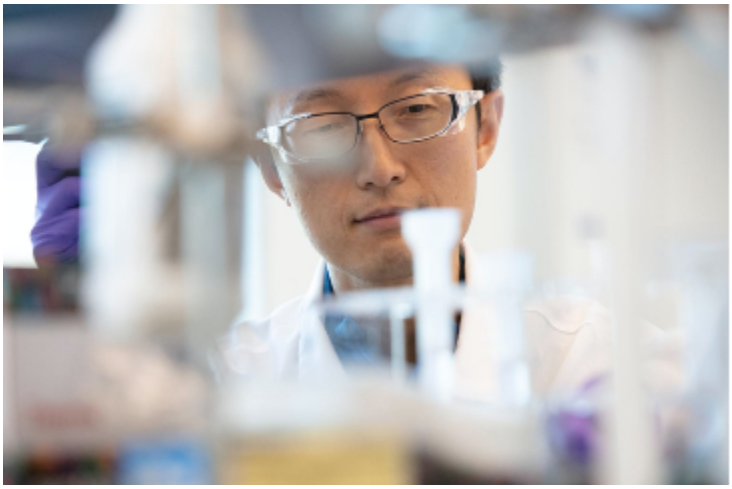

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