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Merck gets FDA nod for Ebola vaccine

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First FDA-approved vaccine for the prevention of Ebola virus disease, marking a critical milestone in public health preparedness and response

The U.S. Food and Drug Administration has announced the approval of Ervebo, the first FDA-approved vaccine for the prevention of Ebola virus disease (EVD), caused by Zaire ebolavirus in individuals 18 years of age and older. Cases of EVD are very rare in the U.S., and those that have occurred have been the result of infections acquired by individuals in other countries who then traveled to the U.S., or health care workers who became ill after treating patients with EVD.

EVD is contagious and is transmitted through direct contact with blood, body fluids and tissues of infected wild animals or people, as well as with surfaces and materials, such as bedding and clothing, contaminated with these fluids. Onset of symptoms of EVD can be sudden and can include fever, fatigue, muscle pain, headache and sore throat. This is followed by vomiting, diarrhea, rash, impaired kidney and liver function and in some cases internal and external bleeding. EVD has an incubation period that ranges from 2 to 21 days. Individuals who provide care for people with EVD, including health care workers who do not use correct infection control precautions, are at the highest risk for infection.

"Ebola virus disease is a rare but severe and often deadly disease that knows no borders. Vaccination is essential to help prevent outbreaks and to stop the Ebola virus from spreading when outbreaks do occur," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research.

"The FDA's approval of Ervebo is a major advance in helping to protect against the Zaire ebolavirus as well as advancing U.S. government preparedness efforts. The research approach used to study the effectiveness and safety of this vaccine was precedent-setting during a public health emergency and may help create a model for future studies under similar circumstances. The FDA is committed to continuing our work across the U.S. government and with our international partners to prevent future Ebola outbreaks and mitigate the current outbreak in the DRC, reflecting our nation's commitment to preparing for and responding to biological threats, like Ebola."

Ervebo is administered as a single-dose injection, and is a live, attenuated vaccine that has been genetically engineered to contain a protein from the Zaire ebolavirus.

The FDA granted this application Priority Review and a Tropical Disease Priority Review Voucher under a program intended to encourage development of new drugs and biologics for the prevention and treatment of certain tropical diseases. The FDA

also granted Breakthrough Therapy designation for Ervebo to facilitate the development and scientific evaluation of the vaccine. Because of the public health importance of a vaccine to prevent EVD, the FDA worked closely with the company and completed its evaluation of the safety and effectiveness of Ervebo in less than six months.

The approval was granted to Merck & Co., Inc