Ervebo® (Ebola Zaire Vaccine, Live) – New vaccine approval

- On December 19, 2019, the FDA announced the approval of Merck's Ervebo (Ebola Zaire Vaccine, Live), 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, and/or blood or plasma transfusions is unknown.

- Ebola virus disease (EVD) 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.

    - 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.

- The efficacy of Ervebo was established in an open-label, randomized cluster vaccination study in the Republic of Guinea during the 2014 outbreak. Patients received either "immediate" or 21-day "delayed" vaccination with Ervebo. The study included 3,537 contacts, and contacts of contacts, of individuals with laboratory-confirmed EVD. Of these, 2,108 were included in 51 immediate vaccination clusters, and 1,429 were included in 46 delayed vaccination clusters.

    - Vaccine efficacy was 100% (95% CI: 63.5 to 100); no cases of confirmed EVD were observed in the immediate vaccination clusters, and 10 confirmed cases of EVD were observed in a total of 4 delayed vaccination clusters between day 10 and day 31 post-randomization.

- In addition, three studies assessed antibody responses to Ervebo, including 477 patients in Liberia, 506 patients in Sierra Leone, and 915 patients in the U.S., Canada, and Spain.

    - The antibody responses among those in the study conducted in Canada, Spain and the U.S. were similar to those among individuals in the studies conducted in Liberia and Sierra Leone.

- Warnings and precautions for Ervebo include management of acute allergic reactions, limitations of vaccine effectiveness, immunocompromised individuals, and transmission.

- The most common injection-site adverse reactions with Ervebo use were injection-site pain, swelling, and redness.

- The most common systemic adverse reactions with Ervebo use were headache, feverishness, muscle pain, fatigue, joint pain, nausea, arthritis, rash, and abnormal sweating.

- The recommended dose of Ervebo is a single 1 mL dose administered intramuscularly, preferably in the deltoid area of the non-dominant arm.

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- Merck plans to launch Ervebo in the third quarter of 2020. Ervebo will be available as a 1 mL suspension in single-dose vials.

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