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Second Ebola Virus Treatment Approved

Announcer:
You're listening to The Drug Report on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to The Drug Report.

The U.S. Food and Drug Administration announced December 21, 2020 its approval of Ebanga (Ansuvimab-zykl), a human monoclonal antibody, for the treatment of *Zaire ebolavirus* (Ebolavirus) infection in adults and children. Ebanga blocks binding of the virus to the cell receptor, preventing its entry into the cell. This is the second drug approved by the FDA for treatment of the deadly virus after nearly seven years has passed since the largest Ebola epidemic broke out in West Africa.

The first drug approved by the FDA for Ebola virus, in October 2020, was Regeneron's Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn), a mixture of three monoclonal antibodies, for infection in adult and pediatric patients. In addition, the FDA approved Merck & Co.'s Ervebo, the first vaccine for the prevention of Ebola virus disease, in December 2019, with support from a study conducted in Guinea during the 2014-2016 Ebola outbreak.

Zaire ebolavirus, commonly known as Ebola virus, is one of four *Ebolavirus* species that can cause a potentially fatal human disease. Ebola virus is transmitted through direct contact with blood, body fluids and tissues of infected people or wild animals, as well as upon surfaces and materials, such as bedding and clothing, contaminated with these fluids. Individuals who provide care for people with Ebola virus, including health care workers who do not use correct infection control precautions, are at the greatest risk for infection.

The most recently approved drug, Ebanga, was originally developed by the National Institutes of Health and was licensed to Miami biotech firm, Ridgeback Biotherapeutics. During an Ebola outbreak in the Democratic Republic of the Congo (DRC) in 2018-2019, Ebanga was studied in a multi-center, open-label, randomized controlled trial. The PALM trial was led by the U.S. National Institutes of Health and the DRC's Institut National de Recherche Biomédicale with contributions from several other international organizations and agencies.

The safety and efficacy of Ebanga was evaluated in 174 participants (120 adults and 54 pediatric patients) with confirmed Ebolavirus infection. Ebanga was administered intravenously as a single 50 mg/kg infusion and 168 participants (135 adults and 33 pediatric patients) received an investigational control. The primary efficacy endpoint was 28-day mortality. The primary analysis population was all patients who were randomized and concurrently eligible to receive either Ebanga or the investigational control during the same time period of the trial. Of the 174 patients who received Ebanga, 35.1% died after 28 days, compared to 49.4% of the 168 patients who received a control.

The most common symptoms among those receiving Ebanga included: fever, tachycardia, diarrhea, vomiting, hypotension, tachypnea and chills; however, these are also common symptoms of Ebolavirus infection. Hypersensitivity, including infusion-related events, can occur in patients taking Ebanga, and treatment should be discontinued in the event of a hypersensitivity reaction.

Patients who receive Ebanga should avoid the concurrent administration of a live virus vaccine against Ebolavirus. There is the potential for Ebanga to inhibit replication of a live vaccine virus and possibly reduce the efficacy of this vaccine.

Ebanga was granted an Orphan Drug designation, which provides incentives to assist and encourage drug development for rare diseases. Additionally, the agency granted Ebanga a Breakthrough Therapy designation.

The PALM trial also evaluated the safety and efficacy of Regeneron's Inmazeb, the first drug approved by the FDA for treatment of Ebola virus. 154 patients received Inmazeb (50 mg of each monoclonal antibody) intravenously as a single infusion, and 168 patients received an investigational control. The primary efficacy endpoint was 28-day mortality. The primary analysis population was all patients who were randomized and concurrently eligible to receive either Inmazeb or the investigational control during the same time period of the trial. Of the 154 patients who received Inmazeb, 33.8% died after 28 days, compared to 51% of the 153 patients who received a control. In the expanded access program, an additional 228 patients received Inmazeb.

The most common symptoms experienced while receiving Inmazeb included: fever, chills, tachycardia, tachypnea , and vomiting; however, these are also common symptoms of Ebola virus infection. Patients who receive Inmazeb should avoid the concurrent administration of a live vaccine due to the treatment's potential to inhibit replication of a live vaccine virus indicated for prevention of Ebola virus infection and possibly reduce the vaccine's efficacy.

Hypersensitivity, including infusion-related events, can occur in patients taking Inmazeb, and treatment should be discontinued in the event of a hypersensitivity reaction.

Inmazeb also received an Orphan Drug designation for the treatment of Ebola virus infection. Additionally, the agency granted Inmazeb a Breakthrough Therapy designation for the treatment of *Zaire ebolavirus* infection.

According to the Antibody Society, an international non-profit supporting antibody-related research and development, Ebanga is the 12th antibody therapeutic to be granted a first approval in the US or EU during 2020.

For The Drug Report, I'm pharmacist, Dr. Linda Bernstein.

Announcer:
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