FDA approves Merck's Zinplava to reduce recurrence of Clostridium difficile infection

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International pharmaceutical company Merck has announced that the U.S. Food and Drug Administration (FDA) has approved Zinplava (its brand name for bezlotoxumab) to reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence. The drug, a monoclonal antibody, was developed by researchers at UMass Medical School's MassBiologics in conjunction with Medarex (now part of Bristol-Myers Squibb), and licensed to Merck in 2009 for development as a potential therapeutic for C. difficile infection.

Merck anticipates making Zinplava available in first quarter 2017.

"Discovering and developing effective new treatments for vexing public health threats has been the mission of MassBiologics since its founding more than 120 years ago," said Mark Klempner, MD, executive vice chancellor for MassBiologics and professor of medicine. "It is exciting and satisfying that all of the creative, hard work of our UMMS faculty and staff has led to this important advance for the treatment of this serious infectious disease."

Clostridium difficile infection, often referred to as C. diff, is caused by bacteria. Symptoms of C. difficile recurrence include mild-to-severe diarrhea, abdominal pain and fever. C. difficile infection occurs most often in patients staying in health care settings, especially hospitals or nursing homes, who recently took certain antibiotics or other medications. The incidence of C. difficile infection is higher in certain patient populations, including people 65 years of age or older, and in patients with compromised immune systems due to an underlying disease or from treatment. Recurrence is a major challenge in C. difficile infection, with approximately one in four patients experiencing a recurrence after the initial episode, and more than 40 percent of these patients having further C. difficile recurrence.

Not an antibiotic, bezlotoxumab is a selective, fully-human monoclonal antibody designed to neutralize C. difficile toxin B. Toxin B can damage the gut wall and cause inflammation, leading to the symptoms of C. difficile enteritis, which include abdominal pain and watery diarrhea.

MassBiologics is the oldest, and only non-profit, FDA-licensed manufacturer of vaccines and biologics in the United States. For more than 100 years, MassBiologics has worked to improve public health through applied research, development and production of biologic products, including vaccines, plasma derivatives, monoclonal antibodies and, most recently, gene therapy vectors. MassBiologics currently manufactures two FDA-licensed vaccines and multiple investigational vaccines, monoclonal antibodies and gene therapy vectors. MassBiologics has been a pioneer in the development of novel monoclonal antibodies, such as bezlotoxumab, for the treatment and prevention of disease.

Provided by University of Massachusetts Medical School