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FDA approves new treatment for hospital acquired infections

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The FDA initially approved Zerbaxa in 2014to treat complicated intra-abdominal infections and for complicated urinary tract infections.

The U.S. Food and Drug Administration has approved a new indication for the previously FDA-approved drug, Zerbaxa (ceftolozane and tazobactam) for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in patients 18 years and older. The FDA initially approved Zerbaxa in 2014 to treat complicated intra-abdominal infections and for complicated urinary tract infections.

The FDA granted the approval of Zerbaxa for the treatment of HABP/VABP to Merck & Co., Inc.

The safety and efficacy of Zerbaxa for the treatment of HABP/VABP, administered via injection, was demonstrated in a multinational, double-blind study that compared Zerbaxa to another antibacterial drug in 726 adult patients hospitalized with HABP/VABP. The study showed that mortality and cure rates were similar between Zerbaxa and the comparator treatment.

Zerbaxa received FDA's Qualified Infectious Disease Product (QIDP) designation for the treatment of HABP/VABP. The QIDP designation is given to antibacterial and antifungal drug products intended to treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act. As part of QIDP designation, the Zerbaxa marketing application for the HABP/VABP indication was granted Priority Review under which the FDA's goal is to take action on an application within an expedited time frame.