

# FDA OKs Cubist antibiotic for serious infections

December 20 2014, by Linda A. Johnson

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The Food and Drug Administration has approved a new medicine to fight complex infections in the abdomen and urinary tract, the fourth antibiotic the agency has approved since May.

Zerbaxa treats serious and [resistant bacteria](#), such as E.coli, that can cause life-threatening infections.

The approval of Zerbaxa on Friday is the second antibiotic approval this year for Cubist Pharmaceuticals, a drugmaker focused on antibiotics. It is being acquired for \$8.4 billion by Merck & Co. of Kenilworth, New Jersey.

New antibiotic approvals are important for public health because the threat of [antibiotic resistance](#) has been growing since the early 1990s. The problem has been fueled by overuse of antibiotics in farm animals to make them grow faster and by inappropriate use of antibiotics for viral infections. Those trends have made some germs difficult and even impossible to kill with antibiotics.

That problem led Congress to pass a law in 2010 that grants expedited review and five years of extra marketing exclusivity to antibiotics and antifungal drugs that treat very serious infections. That exclusivity bars rivals from selling copycat products.

Zerbaxa is the first drug approved under that law that treats Gram-negative bacteria, an especially tough-to-treat group that includes the

germs that cause life-threatening diseases with relatively few treatment options, such as meningitis and cholera. Zerbaxa is not approved to treat meningitis and cholera.

The Infectious Diseases Society of America has set a goal of getting 10 new antibiotics on the market by 2020. The other new antibiotics approved this year are Dalvance from Durata Therapeutics, Orbactiv from The Medicines Co. and another Cubist drug, Sivextro, for common skin infections often acquired in the hospital.

"We must continue to help foster the development of new antibacterial drugs and encourage prudent use of existing treatments to conserve their utility," Dr. Edward Cox, director of the FDA's Office of Antimicrobial Products, said in a statement.

Zerbaxa combines ceftolozane, a new antibiotic, and an existing drug, tazobactam. It was shown in patient tests to work at least as well as two other antibiotics to which it was compared. Its side effects include nausea, diarrhea, headache and fever.

Cubist said it expects to release pricing information on the drug in the near future.

Shares of Cubist rose 2 percent in after-hours trading to \$100.75.

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