FDA NEWS RELEASE

For Immediate Release: April 27, 2012
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FDA approves new antibacterial treatment for plague

The U.S. Food and Drug Administration today approved Levaquin (levofloxacin) to treat patients with plague, a rare and potentially deadly bacterial infection. The agency also approved the drug to reduce the risk of getting plague after exposure to Yersinia pestis, the bacterium that causes the disease.

Plague is extremely rare in most parts of the world, including the United States, with 1,000 to 2,000 cases worldwide each year. The three most common forms of plague are bubonic plague (infection of the lymph nodes), pneumonic plague (infection of the lungs), and septicemic plague (infection of the blood).

Primarily an animal disease, plague can be spread to humans through bites from infected fleas, contact with infected animals or humans, or laboratory exposure. Yersinia pestis also is considered a biological threat agent, which could potentially be used as a bioterrorism agent.

The FDA approved Levaquin for plague under the agency’s Animal Efficacy Rule, which allows efficacy findings from adequate and well-controlled animal studies to be used in cases where it is not feasible or ethical to conduct trials in humans. Because plague is such a rare disease, it would not be possible to conduct adequate efficacy trials in humans.

Levaquin’s approval was based on an efficacy study conducted in African green monkeys that were infected with the plague bacterium in a laboratory setting. Animals were randomly selected to receive a 10-day regimen of Levaquin or placebo within six hours of the onset of fever after being infected. The primary endpoint was survival at the end of the study. Of the 17 monkeys treated with Levaquin, 94 percent survived. None of the seven monkeys treated with placebo survived.

“Today’s approval broadens the available therapeutic treatments for plague,” said Edward Cox, M.D., M.P.H, director of the Office of Antimicrobial Products in FDA’s Center for Drug Evaluation and Research. “It also further demonstrates the usefulness of animal model studies to collect needed efficacy data in cases where human trials are not ethical or feasible.”

Levaquin’s safety has been evidenced by studies and post-marketing information for the drug’s existing medical uses. Common side effects reported in more than 3 percent of patients were nausea, headache, diarrhea, insomnia, constipation, and dizziness.

Serious but rare side effects include tendinitis and tendon rupture, worsening of muscle weakness in people with the neuromuscular disorder myasthenia gravis, allergic reactions, liver damage, abnormality of the blood, effects on the nervous system, and abnormal heart rhythm. However, given that plague is a very serious and often deadly condition, the benefit of Levaquin for treating plague outweighs these potential risks.

The application for Levaquin was granted a priority review by the FDA. It joins streptomycin, doxycycline, tetracycline, and other antibacterial drugs in the tetracycline group as FDA-approved treatments for plague.

Levaquin is manufactured by Raritan, N.J.-based Janssen Pharmaceuticals Inc., a part of Johnson & Johnson.

For more information:
FDA Approved Drugs: Questions and Answers

FDA’s Animal Efficacy Rule

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Page Last Updated: 05/03/2012

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