

FDA approves vaccine to block meningitis strain (Update)

29 October 2014, by Matthew Perrone

Federal health regulators have approved the first vaccine to block a strain of bacteria that has caused sometimes deadly outbreaks of meningitis in college dormitories.

The Food and Drug Administration said Wednesday it cleared Pfizer's Trumenba to prevent a subtype of Meningococcal disease in people ages 10 to 25. When the bacteria infect the bloodstream they cause sepsis. Infection of the lining surrounding the brain and spinal cord is known as meningitis. Symptoms include fever, headache and stiff neck, sometimes followed by nausea and vomiting.

The disease spreads through saliva and other throat fluids via coughing, kissing and sharing utensils. College students living in communal housing are at a slightly higher risk of contracting sepsis and meningitis.

Last year the University of California, Santa Barbara and Princeton University both experienced separate, unrelated outbreaks of meningococcal disease. More than 14,000 students at the universities received a Novartis vaccine already used in Europe, Canada, and Australia, but not approved in the U.S.

Of the 500 cases of meningococcal disease reported in the U.S. in 2012, 160 were caused by the subtype B strain that Trumenba targets. Sanofi and other drugmakers already market vaccines that protect against the other four strains of the bacteria.

"Recent outbreaks of serogroup B meningococcal disease on a few college campuses have heightened concerns for this potentially deadly disease," said Karen Midthun, of the FDA's biologics center.

The disease can be treated with antibiotics, but vaccination is the most effective way to prevent its

spread.

The Centers for Disease Control and Prevention recommends vaccinating preteens at age 11 or 12, followed by a booster shot at age 16. The agency also recommends vaccination for military recruits, patients with a damaged spleen or no spleen and people traveling to countries where meningitis outbreaks are common.

The FDA approved Pfizer's drug as part of its accelerated approval pathway, meaning the vaccine was cleared based on promising preliminary results. As a condition of approval, New York-based Pfizer must conduct additional studies to show that the vaccine works against other meningococcal strains.

Shares of Pfizer Inc. rose 40 cents Wednesday to close at \$29.49.

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