



# Pfizer's Investigational Vaccine Candidate for Clostridium difficile Receives U.S. Food and Drug Administration Fast Track Designation

Thursday, August 28, 2014 - 04:00am

Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the company's investigational Clostridium difficile (C. difficile) vaccine candidate (PF-06425090). Currently in Phase 2 clinical development, the vaccine candidate is designed to prevent C. difficile-associated disease, which can include life-threatening diarrhea and pseudomembranous colitis.

"C. difficile is a growing, difficult-to-treat healthcare-associated infection," said Dr. Emilio Emini, senior vice president of Vaccine Research and Development for Pfizer. "No vaccine is currently available to prevent the infection-associated disease. In the United States alone, there are approximately 250,000 cases of C. difficile-associated disease, resulting in approximately 14,000 deaths each year.<sup>1</sup>"

The FDA's Fast Track approach is a process designed to facilitate the development and expedite the review of new drugs and vaccines intended to treat or prevent serious conditions and address an unmet medical need.<sup>2</sup>

[About Clostridium difficile](#)

Clostridium difficile (klos-TRID-e-um dif-uh-SEEL), often called C. difficile, is the most frequent cause of healthcare-associated infections.<sup>3</sup> C. difficile is a spore-forming, Gram-positive anaerobic bacillus that produces two exotoxins: toxin A and toxin B. It is a common cause of antibiotic-associated diarrhea (AAD) and accounts for 15-25 percent of all episodes of AAD.<sup>4</sup>

Illness from C. difficile most commonly affects older adults in hospitals or in long-term care facilities and typically occurs after use of antibiotic medications. However, studies show increasing rates of C. difficile infection among people traditionally not considered high risk, such as younger and healthy individuals without a history of antibiotic use or exposure to healthcare facilities.<sup>5</sup>

Infection with C. difficile places a significant burden on healthcare facilities<sup>6,7</sup> and has been shown to substantially increase hospital costs, hospital length of stay, and contribute to mortality.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at [www.pfizer.com](http://www.pfizer.com).

DISCLOSURE NOTICE: The information contained in this release is as of August 28, 2014. Pfizer assumes no obligation to update forward-looking statements contained in this

release as the result of new information or future events or developments.

This release contains forward-looking statements about a product candidate, PF-06425090, including its potential benefits, that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results; whether and when any biologics license applications (BLA) may be filed for PF-06425090; whether and when the BLA or any such other applications may be approved by the FDA or other regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by the FDA and other regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of PF-06425090 and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and in our subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and are available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

1. Centers for Disease Control and Prevention. Investigating Clostridium difficile Infections Across the U.S. Available at

<http://www.cdc.gov/features/AntibioticResistanceThreats/index.html>

2. U.S. Food and Drug

Administration, <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingacce>

3. The New England Journal of Medicine; March 27, 2014. Multi-State Point Prevalence Survey of Health Care-Associated Infections. [NEJM.org](http://NEJM.org).

4. Centers for Disease Control and Prevention. Frequently Asked Questions. Available at [http://www.cdc.gov/HAI/organisms/cdiff/Cdiff\\_faqs\\_HCP.html](http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html)

5. The Mayo Clinic. Diseases and Conditions. Available at <http://www.mayoclinic.org/diseases-conditions/c-difficile/basics/definition/con-20029664>

6. Dubberke ER, Butler AM, Reske KA, AgnielD, Olsen MA, D'Angelo G, McDonald LC, Fraser VJ: Attributable outcomes of endemic Clostridium difficile-associated disease in nonsurgical patients, Emerg Infect Dis 2008, 14:1031-1038.

7. Dubberke ER, Butler AM, Reske KA, AgnielD, Olsen MA, D'Angelo G, McDonald LC, Fraser VJ: Short- and long-term attributable costs of Clostridium difficile-associated disease in nonsurgical patients. Clin Infect Dis 2008, 46:497-504

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