Sanofi Pasteur Investigational Vaccine against *Clostridium difficile* (C. diff)
Fact Sheet

Overview

Sanofi Pasteur is developing a vaccine designed to produce an immune response to neutralize the effects of *Clostridium difficile* (C. diff) toxins. Sanofi Pasteur's investigational C. diff infection (CDI) vaccine is entering Phase III clinical development. Vaccination could be an efficacious, cost-effective and important public-health measure to help protect individuals from C. diff, which is emerging as a leading cause of life-threatening, healthcare-associated infections (HAIs) worldwide.[1]

The U.S. Food and Drug Administration (FDA) granted fast-track designation to Sanofi Pasteur's investigational C. diff vaccine candidate in 2010. The FDA's fast-track program is designed to facilitate the development and expedite the review of new drugs and vaccines that are intended to treat or prevent serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

How the Vaccine Works

Like other toxoid vaccines (e.g. tetanus, diphtheria), the investigational C. diff vaccine is designed to produce an immune response that targets the toxins generated by C. diff bacteria, which can cause inflammation of the gut and lead to diarrhea. Ultimately, it may help prevent a future infection from occurring.

Target Population

The target population for this vaccine is adults at risk of CDI, such as elderly with planned elective surgery, long-term care residents, and adults with co-morbidities requiring frequent and/or prolonged antibiotic use or a history of CDI.

Phase I & II Clinical Data

The investigational vaccine has progressed through Phase I and II clinical studies. The most recent Phase II study evaluated the vaccine for safety and immunogenicity in at-risk individuals, which included adults with imminent hospitalization. Plans to publish the results of the Phase II study are in progress.

Phase III Trial (*Cdiffense*)

Sanofi Pasteur's investigational C. diff vaccine candidate is being studied for the prevention of primary disease caused by CDI in a randomized, observer-blind, placebo-controlled, multi-center, multi-national Phase III trial called ***Cdiffense***. Recruitment begins in August 2013 and will last approximately 4.5 years based on the incidence of CDI and necessary follow-up required with patients after vaccination. The trial will include up to 15,000 volunteers across 200 trial sites in 17 countries. For more information, please visit www.Cdiffense.org.

About C. diff

Clostridium difficile (C. diff) is a potentially life-threatening, spore-forming bacterium that causes intestinal disease. The risk of contracting CDI increases with age, antibiotic treatment and time spent in hospitals or nursing homes, where multiple cases can lead to outbreaks.[1] A main source of C. diff is infected patients who release spores into the environment that can then infect other patients. When antibiotics disrupt the gut's normal flora and a person has ingested C. diff spores, the C. diff bacteria multiply and release potent toxins that can damage a patient's intestinal lining and cause C. diff disease.[2]

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[1] Centers for Disease Control and Prevention. Frequently Asked Questions about Clostridium difficile for Healthcare Providers. Centers for Disease Control and Prevention. http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html. Last Updated March 6, 2013. Accessed May 30, 2013.

[2] Delmee M and Warny M. (1995) Clostridium difficile colitis: recent therapeutical and immunologicalconsiderations. Acta Gastroenterol Belg, 58 (3-4), p.313-317.