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 the *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**  
The vaccine stimulates a person’s immune system to fight C. diff toxins upon exposure and ultimately help prevent a future CDI from occurring. Like other toxoid vaccines (e.g., tetanus, diphtheria), this investigational vaccine targets the toxins generated by the C. diff bacteria, which are the cause of symptoms associated with CDI, including inflammation of the gut and diarrhea.

**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 candidate vaccine has progressed through Phase I and II clinical studies. The most recent Phase II clinical 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 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 four years based on the incidence of CDI and necessary follow-up required with patients after vaccination. The trial will include 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 C. diff increases with age, antibiotic treatment, and time spent in hospitals or nursing homes, where multiple cases can lead to outbreaks.² 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 multiplies and releases potent toxins that can damage a patient’s intestinal lining and cause C. diff disease.²