



## Sanofi Pasteur Initiates Phase III Study of Investigational *Clostridium Difficile* Vaccine

*- Cdiffense trial to evaluate vaccine against a leading cause of life-threatening, healthcare-associated infections worldwide -*

**Lyon, France - August 5, 2013** - Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), announced today the initiation of its Phase III clinical program called [Cdiffense](#) to evaluate the safety, immunogenicity and efficacy of an investigational vaccine for the prevention of primary symptomatic *Clostridium difficile* infection (CDI). *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. The investigational vaccine is designed to help protect at-risk individuals from *C. diff*, which is emerging as a leading cause of life-threatening, healthcare-associated infections (HAIs) worldwide.<sup>1</sup>

*C. diff* toxins cause gastrointestinal disease that can lead to death in approximately eight to 15 percent of infected people.<sup>2</sup> Since 20 to 30 percent of patients experience recurrences of CDI, re-hospitalizations and longer hospital stays remain common.<sup>3</sup> Combined data from the United States (U.S.) and European Union (EU) indicate that healthcare systems spend more than \$7 billion annually on CDI acute care.<sup>4,5</sup> Globally, there has been an increase in the incidence and severity of CDI reported in North American,<sup>6</sup> European and Asian countries, possibly due to the emergence of hyper-virulent strains.<sup>7</sup> 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. It ultimately may help prevent a future infection from occurring.

*“With the emergence of difficult-to-manage strains of C. diff, CDI has become more frequent, more severe and more difficult to treat in recent years, raising concerns about how to control it and prevent transmission”,* explained John Shiver PhD, Senior Vice President for Research & Development at Sanofi Pasteur. *“Vaccination could be an efficacious, cost-effective and important public-health measure to protect individuals from C. diff.”*

The [Cdiffense](#) Phase III clinical program has just started recruiting volunteers for a randomized, observer-blind, placebo-controlled, multi-center, multi-national trial that will include up to 15,000 adults at 200 sites across 17 countries. Volunteers for the study should be age 50 or older and planning an upcoming hospitalization or have had at least two hospital stays and have received systemic antibiotics in the past year. For more information on the [Cdiffense](#) trial, please visit [www.Cdiffense.org](http://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.<sup>1</sup> A main source of C. diff is infected patients who release spores into the environment that can then infect other people. 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 person's intestinal lining and cause C. diff disease.<sup>8</sup>

## About Sanofi

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Pasteur, the vaccines division of Sanofi, provides more than 1 billion doses of vaccine each year, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur offers the broadest range of vaccines protecting against 20 infectious diseases. The company's heritage, to create vaccines that protect life, dates back more than a century. Sanofi Pasteur is the largest company entirely dedicated to vaccines. Every day, the company invests more than EUR 1 million in research and development. For more information, please visit: [www.sanofipasteur.com](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://www.sanofipasteur.us)

## Forward Looking Statements

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2012. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

## Contacts:

### Global Media Relations

Alain Bernal

T. +33-4-37-37-50-38

[alain.bernal@sanofipasteur.com](mailto:alain.bernal@sanofipasteur.com)

[www.sanofipasteur.com](http://www.sanofipasteur.com)

### U.S. Media Relations

Susan Watkins

T. +1 570-957-2563

[susan.watkins@sanofipasteur.com](mailto:susan.watkins@sanofipasteur.com)

[www.sanofipasteur.us](http://www.sanofipasteur.us)



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<sup>1</sup> 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](http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html). Last Updated March 6, 2013. Accessed June 26, 2013.

<sup>2</sup> Mitchell BG and Gardner A. (2012) Mortality and Clostridium difficile infection: a review. *Aric journal*.

<sup>3</sup> Garey KW, et al. (2008). Meta-analysis to assess risk factors for recurrent Clostridium difficile infection. *Journal Hospital Infection*, 70, p. 298-304.

<sup>4</sup> Dubberke ER and Olsen MA. Burden of Clostridium Difficile on the Healthcare System. *Clinical Infectious Diseases* 55, no. suppl 2 (2012): S88–S92. doi:10.1093/cid/cis335.

<sup>5</sup> European CDC, Clostridium Difficile basic facts. Accessed June 26, 2013. [http://www.ecdc.europa.eu/EN/HEALTHTOPICS/CLOSTRIDIUM\\_DIFFICILE\\_INFECTIION/BASIC\\_FACTS/Pages/basic\\_facts.aspx](http://www.ecdc.europa.eu/EN/HEALTHTOPICS/CLOSTRIDIUM_DIFFICILE_INFECTIION/BASIC_FACTS/Pages/basic_facts.aspx)

<sup>6</sup> Centers for Disease Control and Prevention. Making Health Care Safer: Stopping C. difficile Infections. Centers for Disease Control and Prevention. <http://www.cdc.gov/VitalSigns/HAI/index.html>. Last Updated August 21, 2012. Accessed June 26, 2013.

<sup>7</sup> Jones AM, Kuijper EJ and Wilcox MH. Clostridium difficile: A European perspective. *Journal of Infection* 2013; 66(2): 115-128. <http://www.sciencedirect.com/science/article/pii/S0163445312003052>. Accessed June 26, 2013.

<sup>8</sup> Delmee M and Warny M. (1995). Clostridium difficile colitis: recent therapeutical and immunological considerations. *Acta Gastroenterol Belg*, 58 (3-4), p. 313-317.