Sanofi Pasteur Initiates Phase III Study of Investigational Clostridium Difficile Vaccine in Japan

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

Tokyo, Japan - January 7, 2016 - Sanofi K.K. (Headquarters: Shinjuku-ku, Tokyo; President: Fabrice Baschiera) (EURONEXT: SAN and NYSE: SNY), announced today that Sanofi Pasteur, the vaccines division of Sanofi, started the initiation of its Phase III clinical program in Japan called Cdiffense to evaluate the safety, immunogenicity and efficacy of an investigational vaccine for the prevention of symptomatic Clostridium difficile infection (CDI). Clostridium difficile (C. diff) is a potentially life-threatening, spore-forming bacterium that causes intestinal disease. The risk of CDI 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 CDI, which is emerging as a leading cause of life-threatening, healthcare-associated infections (HAIs) worldwide.¹

Since 20 to 30 percent of patients experience recurrences of CDI, re-hospitalizations and longer hospital stays remain common.² Although relatively few studies on C. difficile have been performed in Asia, what work has been done demonstrates that CDI is a significant cause of nosocomial disease in Asian countries.³ Sanofi Pasteur’s 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. The phase III clinical trial is designed to determine if the investigational vaccine will help prevent a future infection from occurring.

“With an increased focus on surveillance, we are learning more about the frequency, severity, and cost of C. Diff infections in Japan. Prevention and control through vaccination represents an opportunity to protect patients and reduce healthcare costs associated with C. Diff.”, explained Michael Mullette, Corporate Officer, at Sanofi Pasteur.

The Cdiffense Phase III clinical program has just started recruiting volunteers in Japan for a randomized, observer-blind, placebo-controlled, multi-center, multi-national trial that will include up to 15,000 adults at 200 sites across 20+ countries. Volunteers for the study should be age 50 or older and are planning an upcoming hospitalization or have been in the hospital and received systemic antibiotics in the past year. For more information on the Cdiffense trial, please visit www.Cdiffense.org.

About C. diff
Clostridium difficile (C. diff) is a potentially life-threatening, spore-forming bacterium that causes intestinal disease. 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.³
About Sanofi
Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients’ needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and 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 a broad 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 or www.sanofipasteur.jp

3 Collins et al. Antimicrobial Resistance and Infection Control 2013, 2:21; http://www.aricjournal.com/content/2/1/21