

Sanofi Pasteur starts a phase II study of a vaccine against *Clostridium difficile*

Novel vaccine approach tested in the UK against one of the most common causes of hospital acquired infection in Europe and North America

Lyon France – February 17, 2009 - Sanofi Pasteur, the vaccines division of sanofi-aventis Group (EURONEXT : SAN et NYSE : SNY), announced today that it is sponsoring a phase II clinical study of a vaccine against *Clostridium difficile*, which is among the most common causes of hospital-acquired infection in Europe and North America.

The trial currently conducted in the United Kingdom is investigating the safety and efficacy of sanofi pasteur's *C. difficile* candidate vaccine. While the target indication for the vaccine is primary prevention of *C. difficile* infection (CDI), this trial in infected patients aims at providing early proof of concept of the vaccine approach.

"Treatment of C. difficile infection includes the use of one of two antibiotics. Non-antibiotic approaches for managing C. difficile infection are badly needed since the alteration of the gut flora associated with antibiotics triggers the infection in the first place. There is also considerable concern about the emergence of antibiotic-resistance in C. difficile and other bacteria. Vaccination has the potential to be a very effective strategy to combat gastrointestinal pathologies caused by C. diff. along with better antibiotic stewardship and infection control practices," said Barry Cookson, Director, Laboratory of Healthcare Associated Infections, Centre for Infections, Health Protection Agency and the lead investigator of the trial.

Sanofi Pasteur's candidate vaccine uses a toxoid-based approach, which has been used extensively in sanofi pasteur's licensed vaccines against tetanus, diphtheria and pertussis (whooping cough). This candidate vaccine has successfully completed phase I clinical trials in more than 200 participants to evaluate its safety and immunogenicity.

The incidence of CDI has increased significantly in recent years in both North America and Europe. CDI-related treatments in these two regions of the world are estimated to be costing more than \$7bn a year. The emergence of a hyper-virulent strain of *C. difficile* in 2002 further highlighted the importance of tackling CDI.

About the Clinical Trial

The phase IIb trial involves ~600 participants with acute CDI at ~30 centers across the United Kingdom. Participants will be randomized to 4 study groups, where three groups will receive vaccine, while the fourth group will be given a placebo vaccine. All subjects will receive standard of care antibiotics.

About *C. difficile*

C. difficile is an anaerobic spore-forming bacterium, present asymptomatically in approximately 60% of infants but only ~3% of healthy adults. It belongs to the *Clostridium* family of bacteria, which also includes *C. tetani* (tetanus) and *C. botulinum* (botulism). The *C. difficile* bacteria produce two potent toxins: A and B. When the natural microbial flora of the gut is disturbed, usually as a result of antibiotic treatment, and a patient ingests *C. difficile* spores, the bacteria can multiply and release the two toxins, which cause gastrointestinal pathologies in humans known collectively as CDI.

Hospital-acquired infections caused by *C. difficile* bacteria are a considerable problem in many industrialized countries, including the U.S., Canada, and Europe. It is estimated that *C. difficile* causes about 500,000 cases in the US alone¹ with annual costs to the healthcare system of \$3.2bn.² In the EU, assuming a population of about 460 million people, the healthcare costs of CDI are estimated to be around \$4.4bn per year.³ Additional information is available at the UK Health Protection Agency *C. difficile* information page.⁴

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Pasteur, the vaccines division of sanofi-aventis Group, provided more than 1.6 billion doses of vaccine in 2008, 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 EUR1 million in research and development. For more information, please visit: www.sanofipasteur.com or www.sanofipasteur.us

References:

1. CDC: www.cdc.gov/ncidod/dhqp/id_Cdiff.html
2. O'Brien et al, The Emerging Infectious Challenge of *Clostridium difficile*-Associated Disease in Massachusetts Hospitals: Clinical and Economic Consequences. *Infection Control and Hospital Epidemiology*, 2007; 28(11):1219-1227
3. European Centre for Disease Prevention and Control, Emergence of *Clostridium difficile*-associated disease in North America and Europe, *Clinical Microbiology and Infectious Diseases*, 2006; 12 (Suppl. 6): 2-18
4. HPA: www.hpa.nhs.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1179744911867

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 product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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-aventis’ 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-aventis, 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 EMEA, 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 products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in sanofi-aventis’ annual report on Form 20-F for the year ended December 31, 2007. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

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