



# Pfizer to Present New Data Evaluating Safety, Tolerability and Immunogenicity of its Investigational Staphylococcus aureus Vaccine Candidate at IDWeek 2014™

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Rapid and sustained response in functional antibody titers observed following single-dose administration of a novel, investigational 4-antigen Staphylococcus aureus vaccine (SA4Ag) to healthy adults

Pfizer Inc. (NYSE:PFE) announced today that it will present data from a Phase 1/Phase 2 study evaluating the safety, tolerability and immunogenicity of a single-dose vaccine of Pfizer's investigational 4-antigen Staphylococcus aureus (S. aureus) candidate vaccine (SA4Ag) in healthy adults. The data will be presented at IDWeek 2014™ taking place Oct. 8-12, 2014 in Philadelphia, Pennsylvania.

The SA4Ag vaccine candidate (PF-06290510), currently in Phase 2 clinical trials, was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in February 2014. Fast Track designation is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fill an unmet medical need.<sup>1</sup>

"Staphylococcus aureus is a leading cause of serious health care-associated infections, resulting in a substantial burden to health care systems," said Dr. Kathrin Jansen, senior vice president of the Vaccine Research and Early Development unit for Pfizer. "To date, there is no licensed vaccine available to prevent invasive S. aureus disease. The results from this study are encouraging and support ongoing development of our SA4Ag vaccine

candidate for the prevention of this devastating disease.”

The study results demonstrate that SA4Ag was well tolerated in the 456 healthy adults 18 to 64 years old who randomly received a single intramuscular injection of SA4Ag or placebo. The study also showed rapid rises in functional antibody titers against *S. aureus* that were maintained through at least 12 months.

“Pfizer now has three innovative prophylactic investigational vaccine candidates with the potential to prevent serious diseases — meningococcal group B (MnB), *S. aureus* and *Clostridium difficile* (*C. difficile*) — that have been granted Fast Track designation by the FDA,” said Susan Silbermann, president and general manager for Pfizer Vaccines. “This is a testament to the work of Pfizer’s Vaccine Research and Development unit, who are determined to develop vaccines that focus on diseases of significant unmet medical need around the world.”

#### About *Staphylococcus aureus*

*Staphylococcus aureus* is a leading cause of both health care- and community-associated infections globally and presents a high unmet medical need. Surgical site infection (SSI) complicates 2-5 percent of all surgeries in the United States, resulting in 300,000–500,000 infections each year.<sup>2,3</sup> *S. aureus* has consistently been reported as the most frequent cause of infections at surgical sites and accounts for a large proportion of the morbidity and mortality associated with these infections.<sup>4</sup> The estimated total cost to treat *S. aureus* SSI ranges from \$12 billion to \$14.5 billion annually for U.S. inpatient stays and is associated with nine to 23 additional postoperative hospital days.<sup>5</sup>

#### About IDWeek 2014™

IDWeek 2014™ is an annual meeting of the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA) and the Pediatric Infectious Diseases Society (PIDS). With the theme “Advancing Science, Improving Care,” IDWeek features the latest science and bench-to-bedside approaches in prevention, diagnosis, treatment and epidemiology of infectious diseases, including HIV, across the lifespan. IDWeek 2014 takes place Oct. 8-12 at the Pennsylvania Convention Center in Philadelphia, Pennsylvania. The full name of the meeting is IDWeek 2014™. For more information, visit [www.idweek.org](http://www.idweek.org).

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at [www.pfizer.com](http://www.pfizer.com).

DISCLOSURE NOTICE: The information contained in this release is as of October 10, 2014. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking statements about a product candidate, PF-06290510 and certain other products including their potential benefits, that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results; whether and when any biologics license applications may be filed for PF-06290510 or C. difficile with the FDA or in any other jurisdictions or for MnB in any jurisdictions other than the United States; whether and when any such applications may be approved by the FDA or other regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by the FDA and other regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of PF-06290510 or such other product candidates; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and are available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

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1 U.S. Food and Drug Administration; available  
at <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportant>

2 Martone WJ, Nichols RL, Recognition, prevention, surveillance, and management of surgical site infections; introduction to the problem and symposium overview. Clin Infect Dis 2001; 33 (Suppl 2);S67-8.

3 Weinstein RA. Nosocomial infection update. Emerg Infect Dis 1998; 4:416-20.

4 Is the Burden of Staphylococcus aureus Among Patients With Surgical-Site Infections Growing? John A. Jernigan, MD, MS; Infection Control and Hospital Epidemiology Vol. 25, No. 6 (June 2004) , pp. 457-460 Published by: The University of Chicago Press on behalf of The Society for Healthcare Epidemiology of America; Available at: <http://www.jstor.org/stable/10.1086/502421>.

5 Noskin GA, Rubin RJ, et al. National trends in Staphylococcus aureus infection rates: impact on economic burden and mortality over a 6-year period (1998-2003). Clin Infect Dis. 2007; 45: 1132-1140.

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