Pfizer Begins Phase 2b Study Of Its Investigational Multi-antigen Staphylococcus aureus Vaccine In Adults Undergoing Elective Spinal Fusion Surgery

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Pfizer Inc. (NYSE: PFE) announced today enrollment of the first patient in a Phase 2b clinical trial of its investigational Staphylococcus aureus (S. aureus) multi-antigen vaccine (PF-06290510) in adults undergoing elective spinal fusion surgery. The purpose of the study, named STRIVE (STaphylococcus aureus SuRgical Inpatient Vaccine Efficacy), is to evaluate the safety and efficacy of the vaccine to determine if it prevents postoperative invasive S. aureus infections in patients undergoing elective spinal surgery.1

Surgical Site Infections (SSIs) are a significant and growing concern. SSIs caused by S. aureus account for approximately 20 percent of all SSIs in the U.S., and are associated with an estimated annual treatment cost of $12.3 billion in the U.S.2,3 Patients who suffer such infections due to antibiotic resistant (MRSA) or antibiotic sensitive (MSSA) S.aureus have worse clinical outcomes, including increased mortality in comparison with non-infected patients.4

“We are pleased to take this important next step in the development of ourS. aureus vaccine,” said Dr. Kathrin Jansen, senior vice president and chief scientific officer of Vaccine Research and Development for Pfizer. “To date, there is no licensed vaccine available to prevent invasive S. aureus disease. We believe results from this study, if

positive, will bring us closer to a potential preventive measure for this challenging disease that is associated with considerable morbidity and mortality.”

The primary outcome of the study, with an estimated enrollment of 2600 subjects, will measure the number of subjects in each treatment group with postoperative S. aureus blood stream infections and/or deep incisional or organ/space surgical site infections occurring within 90 days after elective posterior instrumented lumbar spinal fusion. Secondary outcomes will also measure postoperative S. aureus blood stream infections and/or deep incisional or organ/space surgical site infections occurring within 180 days after surgery, and postoperative S. aureus surgical site infections occurring within 90 and 180 days after elective posterior instrumented lumbar spinal fusion. Estimated completion of the study is 2017. More information on the trial can be found at:https://clinicaltrials.gov/show/NCT02388165

Pfizer’s S. aureus vaccine was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in February 2014. The Fast Track process facilitates the development and expedites the review of drugs which treat severe conditions and fulfill an unmet medical need.5 Fast Track designation also enables Pfizer to continue to have ongoing discussions with the FDA on the development of its S. aureus vaccine.

About Staphylococcus aureus Investigational Vaccine

Pfizer’s multi-antigen S. aureus vaccine is designed to prevent a wide-range of clinical disease manifestations, caused by S. aureus, by facilitating killing of the bacteria at the early stages of invasive infection by targeting multiple virulence mechanisms.

About Staphylococcus aureus

Staphylococcus aureus is a leading cause of healthcare-associated infections, resulting in a substantial burden to health care systems. It is a particularly challenging pathogen, with an arsenal of virulence factors that enable host immune evasion and resistance to antibiotics. S. aureus has the potential to induce a wide spectrum of clinical manifestations, ranging from mild skin infections to deep wound and surgical site infections, bacteremia and sepsis, potentially leading to death.

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DISCLOSURE NOTICE: The information contained in this release is as of July 7, 2015. 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 information about an investigational vaccine candidate, PF-06290510, including its potential benefits, that involves 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, without limitation, the ability to meet anticipated clinical trial commencement and completion dates as well as the possibility of unfavorable clinical trial results; whether and when biologics license applications may be filed in any jurisdictions for PF-06290510; whether and when such applications may be approved by 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 regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of PF-06290510; 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, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors 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 available at www.sec.gov andwww.pfizer.com

1 ClinicalTrials.gov: https://clinicaltrials.gov/show/NCT02388165

2 Noskin GA et al. Clin Infect Dis. 2007;45:1132-1140.

3 A report from the National Nosocomial Infections Surveillance (NNIS) System. Am J Infect Control. 1996;24(5):380-388.

4 Anderson DJ. Kaye, K,S et al. Clinical and Financial Outcomes Due to Methicillin Resistant Staphylococcus aureus Surgical Site Infection: A Multi-Center Matched Outcomes Study. PLoS ONE. 2009; 4(12): e8305.

5 U.S. Food and Drug Administration; available athttp://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportan

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