Pfizer Announces Positive Top-Line Results Of Landmark Community-Acquired Pneumonia Immunization Trial In Adults (CAPiTA) Evaluating Efficacy Of Prevenar 13*

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Data to Be Presented at 9th International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) on March 12, 2014

Pfizer Inc. (NYSE: PFE) today announced that the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA), the landmark study of approximately 85,000 subjects evaluating the efficacy of Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) in adults 65 years of age and older, achieved its primary clinical objective and both secondary clinical objectives. CAPiTA is the largest double-blind, randomized, placebo-controlled vaccine efficacy trial ever conducted in adults.

The primary objective of the study was to demonstrate efficacy of Prevenar 13 against a first episode of vaccine-type community-acquired pneumonia (CAP). The CAPiTA study also met both secondary objectives, which were efficacy against (i) a first episode of non-bacteremic/non-invasive vaccine-type CAP and (ii) a first episode of vaccine-type invasive pneumococcal disease (IPD).

Vaccine-type CAP (VT-CAP) was defined as CAP caused by any *S. pneumoniae* serotype included in the vaccine. Non-bacteremic/non-invasive VT-CAP was defined as CAP in which vaccine-type *S. pneumoniae* caused the pneumonia, but was not detected concurrently in the bloodstream or any other normally sterile site. Vaccine-type IPD was defined as a case in which vaccine-type *S. pneumoniae* was present in the bloodstream or any other normally sterile site, with or without pneumonia.

“We are pleased with the outcome of the CAPiTA study, which demonstrated that Prevenar 13 can prevent vaccine-type pneumococcal community-acquired pneumonia in adults,” said Dr. William Gruber, senior vice president, Vaccine Clinical Research, Pfizer.

“Pneumococcal pneumonia is a significant cause of illness and death in adults around the world, and the potential to reduce the burden of this disease through direct vaccination of adults represents a meaningful public health benefit,” said Dr. Emilio A. Emini, senior vice president, Vaccine Research and Development, Pfizer. “Pfizer looks forward to sharing the CAPiTA data with U.S. and worldwide regulatory authorities, and vaccine technical committees, to help inform decisions regarding potential Prevenar 13 label and recommendation updates.”

The CAPiTA data will be an important component in any consideration of potential new or updated Prevenar 13 recommendations for adults. In addition, other key factors will be taken into consideration, such as the current burden of pneumococcal disease in adults.

Prevnar 13 was licensed by the FDA under an accelerated approval process to address an unmet medical need in older adults. As a requirement of the accelerated approval pathway, Pfizer conducted CAPiTA to verify clinical benefit.

Detailed results will be presented at the 9th International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) in Hyderabad, India, on March 12, 2014, during the late-breaker session from 2:30 p.m. to 4:10 p.m. IST/5 a.m. to 6:40 a.m. EDT.

About Pneumococcal Disease

Pneumococcal disease refers to a group of illnesses caused by *S. pneumoniae* bacteria.[1] Invasive pneumococcal disease occurs when bacteria enter the bloodstream, or another site that is normally sterile.[2] Non-invasive pneumococcal pneumonia occurs when the bacteria cause infection in the lungs but are not detected in the blood concurrently.1 In adults, pneumonia is the most common presentation of pneumococcal disease.1 For every one case of invasive pneumococcal pneumonia in adults, it is estimated that at least three cases of non-invasive pneumococcal pneumonia occur.[3] While non-invasive forms of pneumococcal disease are typically more common, the invasive types of disease are generally more severe.[4]

About CAPiTA

As part of its regulatory commitments under the FDA's accelerated approval program, Pfizer conducted the CAPiTA study, which was designed to evaluate the efficacy of Prevnar 13 in the prevention of vaccine-type pneumococcal pneumonia. CAPiTA is the largest double-blind, randomized, placebo-controlled vaccine efficacy trial ever conducted in adults. It involved approximately 85,000 subjects aged 65 years and older. The trial was conducted by Julius Clinical, a spin-off of the Julius Center for Health Sciences and Primary Care, a division of the University Medical Center Utrecht in the Netherlands. Fifty-eight sentinel hospitals were used for the surveillance of CAP and IPD. The safety profile of Prevenar 13 observed in CAPiTA was consistent with studies previously conducted in adults. The safety data will be included in the presentation at ISPPD.

About Prevenar 13

Prevenar 13 was first introduced for use in infants and young children in December 2009 in Europe and is now approved for such use in more than 120 countries worldwide, including the United States and Japan. It is the most widely used pneumococcal conjugate vaccine (PCV) in the world, and more than 640 million doses of Prevenar 7-valent/Prevenar 13 have been distributed worldwide. In addition, Prevenar 13 is approved for use in adults 50 years of age and older in more than 90 countries, and is also approved in the United States and European Union (EU) for use in older children and

adolescents aged 6 to 17 years. Recently, Prevenar 13 was also approved in the EU for use in adults 18 to 49 years of age.

Indications for Prevnar 13®

· Prevnar 13® is a vaccine approved for adults 50 years of age and older for the prevention of pneumococcal pneumonia and invasive disease caused by 13 *Streptococcus pneumoniae* strains (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). This indication is based upon immune responses to the vaccine

· For children 6 weeks through 17 years of age, Prevnar 13® is approved for the prevention of invasive disease caused by the 13 vaccine strains, and for children 6 weeks through 5 years for the prevention of otitis media caused by 7 of the 13 strains

· Prevnar 13® is not 100% effective and will only help protect against the 13 strains included in the vaccine

· Effectiveness when given less than 5 years after a pneumococcal polysaccharide vaccine is not known

Important Safety Information

· Prevnar 13® should not be given to anyone with a history of severe allergic reaction to any component of Prevnar 13® or any diphtheria toxoid–containing vaccine

· Children and adults with weakened immune systems (eg, HIV infection, leukemia) may have a reduced immune response

· In adults, immune responses to Prevnar 13® were reduced when given with injected seasonal flu vaccine

· In adults, the common side effects were pain, redness, or swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, chills, or rash

· A temporary pause of breathing following vaccination has been observed in some infants born prematurely

· The most commonly reported serious adverse events in infants and toddlers were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%)

· In children 6 weeks through 17 years, the most common side effects were tenderness, redness, or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever.

· Ask your health care provider about the risks and benefits of Prevnar 13®. Only a health care provider can decide if Prevnar 13® is right for you

For the full prescribing information for Prevnar 13, please click here http://www.pfizer.com/products/#prevnar13.

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[*] Trademark. Prevnar 13® is the trade name in the United States, Canada, and Taiwan.

DISCLOSURE NOTICE: *The information contained in this release is as of February 24, 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 information that involves substantial risks and uncertainties regarding Prevnar 13/Prevenar 13, including its potential benefits, and about the CAPiTA trial. Such risks and uncertainties include, among other things, uncertainty concerning the commercial impact of the results of the CAPiTA trial; uncertainty concerning whether and when regulatory authorities in various jurisdictions will update the label and vaccine technical committees in various jurisdictions will update their recommendations with respect to the use of Prevnar 13/Prevenar 13 in adults based on the results of the CAPiTA trial and other factors; whether and when regulatory submissions may be made in jurisdictions other than the U.S. for Prevenar 13 for the prevention of pneumococcal pneumonia in adults caused by the 13 serotypes in Prevenar 13, and whether and when regulatory authorities in such jurisdictions will approve any such submissions, as well as their decisions regarding labeling and other matters that could affect the availability and commercial potential of that additional indication for Prevenar 13 in those jurisdictions; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012 and in its subsequent reports on Form 10-Q and Form 8-K.

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[1] Centers for Disease Control and Prevention. Pneumococcal disease. In: Atkinson W, Wolfe S, Hamborsky J, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* 12th ed., second printing. Washington DC: Public Health Foundation, 2012.

[2] Musher DM. *Streptococcus pneumoniae.* In: Mandell GL, Douglas JE, Dolin R, eds. *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases.* 7th ed.

Elsevier: 2010.

[3] Said MA, Johnson HL, Nonyane BAS, et al. Estimating the burden of pneumococcal disease among adults: a systematic review and meta-analysis of diagnostic techniques. PLoS ONE. 2013;8(4):e60273.

[4] World Health Organization (WHO). Immunization, Vaccines and Biologicals. Pneumoccocal Vaccines. 2003.

http://archives.who.int/vaccines/en/pneumococcus.shtml.

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