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Pfizer Presents Detailed Results From Landmark Community-Acquired Pneumonia Immunization Trial In Adults (CAPiTA) Evaluating Efficacy Of Prevenar 13*

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Study Findings, Presented at ISPPD, Demonstrate that Prevenar 13 Can Prevent Vaccine-Type Community-Acquired Pneumonia

Pfizer Inc. (NYSE:PFE) today presented detailed results of the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA), the landmark study of approximately 85,000 subjects, demonstrating that Prevenar 13 * (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) prevented a first episode of vaccine-type community-acquired pneumonia (CAP) in adults 65 years of age and older, the study's primary objective. This trial is the first in adults to clearly demonstrate a significant reduction in vaccine-type pneumococcal CAP, and importantly, non-bacteremic/non-invasive vaccine-type pneumococcal CAP. Results were presented during the late-breaker session at the 9th International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) in Hyderabad, India, on March 12, 2014.

CAPiTA (Community-Acquired Pneumonia Immunization Trial in Adults) also met both of its secondary study objectives –significant reduction in (i) non-bacteremic/non-invasive vaccine-type pneumococcal CAP and (ii) vaccine-type invasive pneumococcal disease (IPD).

Regarding the study's primary objective, there were 45.56 percent fewer first episodes of vaccine-type CAP among Prevenar 13-vaccinated subjects than in subjects who received placebo (P=0.0006). Regarding the study's secondary objectives, the Prevenar 13 group experienced 45.00 percent fewer first episodes of non-bacteremic/non-invasive vaccine-type CAP (P=0.0067) and 75.00 percent fewer first episodes of vaccine-type IPD (P=0.0005) compared with the placebo group. The safety profile of Prevenar 13 in this study was consistent with studies previously conducted in adults.

Additional data showed reductions in vaccine-type CAP, non-bacteremic/non-invasive vaccine-type CAP, and vaccine-type IPD for up to four years after vaccination among subjects who received Prevenar 13.

"With the aging of the population, hospitalizations due to pneumococcal pneumonia represent a growing burden to public health systems. Evidence from this study is particularly important for a population in which age-related decline of the immune system makes it difficult to prevent disease," said Dr. Emilio A. Emini, senior vice president, Vaccine Research and Development, Pfizer.

“This study demonstrated that vaccination with Prevenar 13 can prevent a significant portion of pneumococcal community-acquired pneumonia in adults aged 65 and older, which is an important global public health goal,” said principal investigator Prof. Marc Bonten, professor of Molecular Epidemiology of Infectious Diseases, Department of Medical Microbiology, Julius Center for Health Sciences & Primary Care, University Medical Center Utrecht in the Netherlands.

The CAPiTA (Community-Acquired Pneumonia Immunization Trial in Adults) study data will be an important part of any consideration of potential new or updated recommendations for Prevenar 13 in adults. Other key factors also are expected to be taken into consideration, including the current burden of pneumococcal disease in adults.

About CAPiTA (Community-Acquired Pneumonia Immunization Trial in Adults)

In 2011, Prevnar 13 was licensed by the U.S. Food and Drug Administration 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 (Community-Acquired Pneumonia Immunization Trial in Adults) to verify clinical benefit.

This was a parallel-group, randomized, placebo-controlled, double-blind, single-center trial in which subjects aged 65 years and older were randomly assigned to receive a single dose of either Prevnar 13 or placebo. A total of 84,496 subjects were enrolled. 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.

Vaccine-type CAP (VT-CAP) was defined as CAP caused by any *Streptococcus pneumoniae* serotype included in the vaccine. Non-bacteremic/noninvasive 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.

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 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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DISCLOSURE NOTICE: *The information contained in this release is as of March 12, 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 (Community-Acquired Pneumonia Immunization Trial in Adults) trial. Such risks and uncertainties include, among other things, uncertainty concerning the commercial impact of the results of the 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 (Community-Acquired Pneumonia Immunization Trial in Adults) 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 for the fiscal year ended December 31, 2013 and in its subsequent reports on Form 10-Q and Form 8-K.

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

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. Pneumococcalvaccines. 2003. http://archives.who.int/vaccines/en/pneumococcus.shtml.

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