Results of Pfizer’s Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA) Published in the New England Journal of Medicine

Wednesday, March 18, 2015 - 01:04pm

Study Showed a Significant Reduction in Vaccine-Type Pneumococcal Community-Acquired Pneumonia in Older Adults Given Prevenar 13

Pfizer Inc. (NYSE:PFE) today announced the publication of findings from its Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA) in the March 19 issue of The New England Journal of Medicine. The study, conducted in collaboration with Julius Clinical and the University Medical Centre Utrecht in the Netherlands, investigated the efficacy of immunization with Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) to prevent a first episode of vaccine-type pneumococcal community-acquired pneumonia (CAP), including non-bacteremic/non-invasive CAP, and vaccine-type invasive pneumococcal disease (IPD) in adults aged 65 years and older. The study achieved its primary and secondary objectives.1

“Since our immune system naturally weakens with age, the likelihood of getting infections increases even in otherwise healthy, active older adults,2 with pneumococcal community-acquired pneumonia representing a significant cause of illness in this population,3,4,5” said principal investigator Marc Bonten, M.D., Ph.D., 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 results of this study demonstrated that immunization with Prevenar 13

reduced the risk of pneumococcal community-acquired pneumonia and invasive pneumococcal disease caused by the 13 serotypes in the vaccine among adults aged 65 years and older.1”

Pfizer conducted the CAPiTA study (Community-Acquired Pneumonia Immunization Trial in Adults) as part of its regulatory commitments to global regulatory authorities. In February 2015, the European Commission approved a new indication for the use of Prevenar 13 for the prevention of vaccine-type pneumococcal pneumonia in adults, and the Summary of Product Characteristics was updated to include these efficacy data. The results also have been submitted to the U.S. Food and Drug Administration and regulatory agencies in other major markets, including Australia and Canada, for inclusion in the product’s labeling.

“This landmark study was a significant achievement,” said William Gruber, M.D., senior vice president, Vaccine Clinical Research, Pfizer. “The study was one of the largest double-blind, randomized, placebo-controlled vaccine efficacy trials ever conducted in older adults. Its successful execution reflected the integration of clinical study design with supporting basic research-driven applications.”

As reported in the publication, for the primary endpoint, there were 45.6 percent fewer first episodes of vaccine-type CAP among Prevenar 13-vaccinated subjects than in subjects who received placebo ($P<0.001$). Regarding the study’s secondary endpoints, the Prevenar 13 group experienced 45.0 percent fewer first episodes of non-bacteremic/non-invasive vaccine-type CAP ($P=0.007$) and 75.0 percent fewer first episodes of vaccine-type IPD ($P<0.001$) compared with the placebo group. The safety profile of Prevenar 13 in this study was consistent with studies previously conducted in adults.1

“Vaccine-type pneumococcal community-acquired pneumonia still represents a substantial disease burden in older adults,3,4,5,6” said Luis Jodar, Ph.D., global vice president, Vaccines, Pfizer Global Medicines Development Group and Medical/Scientific Affairs. “The recent U.S. Advisory Committee on Immunization Practices recommendation to vaccinate adults 65 years and older with Prevenar 13 recognizes the opportunity to reduce this disease burden. We continue to engage in discussions with other vaccine recommending bodies around the world on the potential to provide a meaningful public health benefit through immunization with Prevenar 13.”

Streptococcus pneumoniae, also known as pneumococcus, is the most common bacterial cause of community-acquired pneumonia.7 Pneumococcal CAP is one of the leading

causes of death and hospitalization worldwide.8 Pneumococcal pneumonia can be classified as non-invasive, when bacteria cause infection in the lungs but are not detected in the blood concurrently, or invasive, when bacteria also enter the bloodstream (bacteremic pneumonia) or another normally sterile site in the body.9 While non-invasive forms of pneumococcal disease are typically more common, the invasive types of disease are generally more severe.10

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

This was a parallel-group, randomized, placebo-controlled, double-blind trial in which subjects aged 65 years and older were randomly assigned to receive a single dose of either Prevenar 13 or placebo. A total of 84,496 subjects were enrolled. The trial was conducted by Julius Clinical, an academic research organization affiliated with the University Medical Center Utrecht (UMCU) in the Netherlands. Fifty-nine sentinel hospitals were used for the surveillance of CAP and IPD.1

Vaccine-type CAP (VT-CAP) was defined as CAP caused by any Streptococcus 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.1

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, Canada, Australia and Japan. It is the most widely used pneumococcal conjugate vaccine (PCV) in the world, and more than 750 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 it is also approved in the United States, European Union (EU) and other countries for use in older children and adolescents aged 6 to 17 years. Prevenar 13 is 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 in the U.S. 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 in the U.S. 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 18, 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 regarding Prevnar 13/Prevenar 13, 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, uncertainties concerning the commercial impact of the results of the CAPiTA (Community-Acquired Pneumonia Immunization Trial in Adults) trial and the expanded indication in the EU; uncertainty concerning whether and when regulatory authorities in various other jurisdictions will update the label and whether and when vaccine technical committees in various jurisdictions (other than the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices) 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 additional jurisdictions 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 jurisdictions where such applications are pending or submitted will approve any such submissions, as well as their decisions regarding labeling and other matters that could affect the availability or 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, 2014 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 available at www.sec.gov and www.pfizer.com.

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

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