A Study Analyzing Observational Data Shows Real-World Effectiveness of Prevnar® 13 in Adults Age 65+

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Study Finds Prevnar 13 was Associated With Reduced Risk of Hospitalization From Vaccine-Type Community-Acquired Pneumonia in Older Adults 1

Pfizer Inc. (NYSE: PFE) announced today that results from a study analyzing real-world effectiveness data found that Prevnar 13® (pneumococcal 13-valent conjugate vaccine [diphtheria CRM197 Protein]) reduced the risk of hospitalization from vaccine-type pneumococcal community-acquired pneumonia (CAP) by 73% (95% CI: 12.8−91.5%) in adults aged 65 and older.1 Importantly, Prevnar 13 (PCV13) worked under real-world conditions where people received pneumococcal vaccination as advised by their health care providers, and many had underlying medical conditions that increase the risk for pneumococcal pneumonia.1 The results were published in Clinical Infectious Diseases .

The study, conducted jointly between the University of Louisville School of Medicine and Pfizer, was designed as a test-negative case-control study and provides evidence supporting the findings of the landmark randomized, controlled Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA).1 CAPiTA was one of the largest vaccine efficacy trials ever conducted in older adults and demonstrated a significant reduction by 45.6% (95.2% CI: 21.8-62.5; $p<0.001$) in vaccine-type pneumococcal CAP in adults vaccinated with PCV13.2 The Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA) excluded people with high-risk medical conditions.2 The safety profile of PCV13 in CAPiTA was consistent with studies previously conducted in adults.2

“The new effectiveness data further demonstrate that vaccinating adults aged 65 and older against pneumococcal pneumonia with PCV13 could help prevent hospitalization and save lives,”1 said Dr. Julio A. Ramirez, Chief, Division of Infectious Diseases, University of Louisville School of Medicine, and one of the study authors. “Specifically, based on a 73% vaccine effectiveness observed in this study, we estimate that PCV13 vaccination in adults 65+ might prevent thousands of CAP-related hospitalizations.”1

Streptococcus pneumoniae, also known as pneumococcus, is the most common bacterial cause of CAP.3,4 Pneumococcal pneumonia can be classified as non-invasive, when bacteria cause infection in the lungs but are not detected in the blood, or invasive, when bacteria also enter the bloodstream (bacteremic pneumonia) or another normally sterile site in the body.5 For every one case of invasive pneumococcal pneumonia in adults, it is estimated that at least three cases of non-invasive pneumococcal pneumonia occur.6 While non-invasive forms of pneumococcal disease are typically more common, the invasive types of disease are generally more severe.7

“These results complement the Community-Acquired Pneumonia Immunization Trial in Adults study, suggesting that PCV13 is effective under the real-world circumstances of an immunization program, including a percentage of individuals with high-risk conditions that were excluded from the Community-Acquired Pneumonia Immunization Trial in Adults analysis,”1 said Dr. Luis Jodar, Chief Medical and Scientific Affairs Officer, Vaccines Medical Development, Scientific and Clinical Affairs, Pfizer Inc. “These findings, as well as the continuous circulation of the 13 serotypes included in PCV13 among adults, confirm the importance of direct vaccination in this age group.”

About the Test-Negative Design Study in Older Adults

The study was nested within a population-based surveillance study of adults in Louisville, Kentucky, United States, who were hospitalized with CAP. The population-based surveillance study prospectively enrolled adults in Louisville, Kentucky who were hospitalized with CAP in one of nine adult acute-care hospitals between October 7, 2013 and September 30, 2016. The nested case-control sub-study analyzed a subset of CAP patients enrolled between April 1, 2015 and April 30, 2016. The study used an established measure of vaccine effectiveness known as a test-negative design. In this study, patients hospitalized with CAP had routine cultures performed as well as a urine antigen detection test to determine if they had infections with pneumococcal serotypes included in the vaccine, PCV13. Patients with pneumonias caused by pneumococcal serotypes included in PCV13 were considered “cases,” and “control” subjects were patients with CAP who tested negative for PCV13 serotypes.1

Considerations for Using Real-World Data: Clinical studies analyzing real-world data have the potential to supplement randomized trials by providing additional information about how a medicine performs in routine medical practice. Clinical studies analyzing real-world data have several limitations. For example, the source and type of data used may limit the generalizability of the results and of the endpoints. Due to these limitations, real-world data analyses are not generally used as stand-alone evidence to validate the efficacy and/or safety of a treatment.

In the study period, there were a total of 2,034 CAP hospitalizations with a median age of 76 years. Researchers identified PCV13 serotypes in 68 (3.3%) of patients who served as the case subjects. Cases were less likely to have received PCV13 vs. controls (4.4% vs. 14.5%, P=0.02). This indicated that PCV13 use in adults aged 65 and older can prevent 73% of CAP caused by PCV13 serotypes.1

Additional information on the study population included:

88% had at least one underlying risk factor for pneumococcal pneumonia, including chronic obstructive pulmonary disease (53%), coronary artery disease (35%), congestive heart failure (32%), and diabetes (32%)1 46% were immunocompromised, with chronic kidney disease (23%) and cancer (19%) being the most common conditions1 21% had previously received another pneumococcal vaccine, PPSV23 in the past 5 years; the effectiveness of PCV13 was not affected by prior use of PPSV23.1 As noted in the United States Prescribing Information, prior receipt of PPSV23 within 1-year results in diminished immune responses to PCV13 compared to PPSV23-naïve individuals8 The median hospital stay for CAP was 6 days1 6.5% of patients with CAP died during the initial hospital stay and 12.7% died within 30 days1
In 2014, the U.S. Centers for Disease Control and Prevention’s Advisory Committee on Immunizations Practices (ACIP) recommended routine immunization with PCV13 for adults 65 years and older based on the data from the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA).9 This follows the ACIP 2012 recommendation for routine vaccination with PCV13 for adults 19 years of age and older with immunocompromising conditions (eg, HIV, chronic renal failure, cancer), functional or anatomic asplenia (eg, sickle cell disease), cerebral spinal fluid leak, and Cochlear implants.10

About Prevnar 13 ®

Prevnar 13® (pneumococcal 13-valent conjugate vaccine [diphtheria CRM197 Protein]) was approved in the U.S. in February 2010 for use in infants and young children.

The vaccine is indicated in children 6 weeks through 17 years (prior to the 18th birthday) for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae (S. pneumoniae) serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for children 6 weeks through 5 years of age (prior to the 6th birthday) for the prevention of otitis media caused by 7 of the 13 serotypes only (4, 6B, 9V, 14, 18C, 19F, and 23F).

In adults 18 years of age and older, Prevnar 13® is indicated for active immunization for the prevention of pneumonia and invasive disease caused by S. pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F.

Limitations of Use and Effectiveness

Prevnar 13® does not protect against disease caused by S. pneumoniae serotypes that are not in the vaccine
Prevnar 13® is the trade name in the United States, Canada, and Taiwan. Outside these countries, it is marketed as Prevenar 13® (pneumococcal polysaccharide conjugate vaccine [13 – valent, adsorbed]). It is approved in the EU and other countries for use in infants, older children and adolescents aged 6 to 17 years. In addition, Prevenar 13 is approved for use in adults 50 years of age and older in more than 100 countries. Prevenar 13 is approved in the EU and more than 40 other countries for use in adults 18 to 49 years of age.

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, the most common side effects were pain, redness, and swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, vomiting, fever, chills, and 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 healthcare provider about the risks and benefits of Prevnar 13®. Only a healthcare provider can decide if Prevnar 13® is right for you or your child

For the full Prescribing Information for Prevnar 13®, please click here http://labeling.pfizer.com/ShowLabeling.aspx?id=501.

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DISCLOSURE NOTICE: The information contained in this release is as of May 22, 2018. 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 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 regarding commercial impact; the uncertainties inherent in research and development, including, without limitation, the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; uncertainties regarding the ability to obtain or maintain recommendations from vaccine technical committees, recommending bodies and other public health authorities regarding Prevnar 13 and uncertainties regarding the commercial impact of any such recommendations; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of Prevnar 13/Prevenar 13; 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, 2017 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 U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com

_____ 1 McLaughlin J, Jiang Q, Isturiz RE, et al. Effectiveness of 13-Valent Pneumococcal Conjugate Vaccine Against Hospitalization for Community-Acquired Pneumonia in Older US Adults: A Test-Negative Design. Clinical Infectious Diseases. doi: 10.1093/cid/ciy312. https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/ciy312. Accessed May 22, 2018. 2 Bonten MJM, Huijts SM, Bolkenbaas M, et al. Polysaccharide Conjugate Vaccine against Pneumococcal Pneumonia in Adults. N Engl J Med. 2015;372(12):1114-1125. doi:10.1056/NEJMoa1408544. 3 World Health Organization. International travel and health. Pneumococcal disease. http://www.who.int/ith/diseases/pneumococcal/en/. Accessed May 22, 2018. 4 Welte T, Torres A, Nathwani D. Clinical and economic burden of community-acquired pneumonia among adults in Europe. Thorax. 2012;67(1):71-79. 5 Centers for Disease Control and Prevention. MMWR Recommendations and Reports. Prevention of pneumococcal disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). 1997;46(RR-8):1-24. 6 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. 7 World Health Organization. Immunization, vaccines and biologicals. Pneumococcal vaccines. Available at: http://archives.who.int/vaccines/en/pneumococcus.shtml. Accessed May 22, 2018. 8 PREVNAR 13- pneumococcal 13-valent conjugate vaccine injection, suspension. Wyeth Pharmaceutical Division of Wyeth Holdings LLC, a subsidiary of Pfizer Inc. Full prescribing information. 8/2017. 9 Tomczyk S, Bennett NM, Stoecker C, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkly Rep. 2014;63(37):822-825. 10 Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine for adults with immunocompromising conditions. http://stacks.cdc.gov/view/cdc/29139. October 12, 2012. Accessed May 22, 2018.

Pfizer Inc. Media: Jessica Smith, (212) 733-6213jessica.m.smith@pfizer.com or Investor: Ryan Crowe, (212) 733-8160ryan.crowe@pfizer.com