Pfizer Logo

Pfizer Receives FDA Approval to Extend Use of Prevnar 13® for Prevention of Pneumococcal Pneumonia and Invasive Disease in Adults 50 Years and Older

Friday, December 30, 2011 - 12:17am

First pneumococcal conjugate vaccine for adults 50+ has potential to help address high incidence of pneumococcal pneumonia

"Pneumococcal disease, including pneumonia, in adults 50 years and older represents a significant personal and societal health burden in the United States. The FDA approval of Prevnar 13 for these adults offers the potential to contribute to the health of millions of aging Americans,"

(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) has granted approval of the Company's pneumococcal conjugate vaccine Prevnar 13®* (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]) as a single dose for use in adults. Prevnar 13 is indicated for adults 50 years of age and older for active immunization for the prevention of pneumonia and invasive disease caused by the 13 *Streptococcus pneumoniae* (*S. pneumoniae*) serotypes contained in the vaccine.

"Pneumococcal disease, including pneumonia, in adults 50 years and older represents a significant personal and societal health burden in the United States. The FDA approval of Prevnar 13 for these adults offers the potential to contribute to the health of millions of aging Americans," said Ian Read, chairman and chief executive officer, Pfizer Inc. "This approval is representative of Pfizer's dedication to discovering and bringing to market life-changing medicines and vaccines."

Pneumococcal disease (PD) is a leading public health issue in adults 50 years of age and older, a population rapidly increasing in the United States. In this population, there are estimated to be hundreds of thousands of *S. pneumoniae* infections per year, including more than 440,000 cases of pneumococcal pneumonia, accounting for an estimated 200,000 emergency department visits and 300,000 hospitalizations.

"Clearly, there remains a high incidence of pneumococcal pneumonia in this adult population," said Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer Inc. "Prevnar 13 was licensed for adults 50 years and older by the FDA under an accelerated approval pathway because of its potential to help address this significant disease burden."

Pfizer's application to the U.S. FDA was based on safety and immunogenicity studies involving approximately 6,000 adults 50 years of age and older. In these Phase 3 trials, vaccination with Prevnar 13 was shown to induce a functional antibody response to the 13 serotypes contained in the vaccine in adults 50 years of age and older, including individuals previously vaccinated with the conventional pneumococcal polysaccharide vaccine (PPSV) and those naïve to pneumococcal vaccines. The effectiveness of Prevnar 13 administered less than five years

after PPSV is not known.

The expanded indication approved by the U.S. FDA is based on immune responses elicited by Prevnar 13, and there have been no controlled trials in adults demonstrating a decrease in pneumococcal pneumonia or invasive pneumococcal disease after vaccination with Prevnar 13.

Pfizer is currently conducting the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA) to fulfill requirements under the accelerated approval pathway. CAPiTA is an efficacy trial involving more than 84,000 subjects designed to evaluate whether Prevnar 13 is effective in preventing the first episode of community-acquired pneumonia (CAP) caused by the 13 pneumococcal serotypes contained in the vaccine.

In addition, Pfizer has agreed, as a post-marketing commitment in connection with the approval by the U.S. FDA, to conduct a study evaluating concomitant use of Prevnar 13 and TIV (annual trivalent inactivated influenza vaccine) in adults 50 years of age and older who have been previously immunized with PPSV.

“As adults grow older they become more susceptible to infectious diseases, such as pneumococcal pneumonia, due to their aging immune systems,” said Thomas M. File, Jr., M.D., M.S., president-elect, National Foundation for Infectious Diseases. “As a conjugate vaccine, Prevnar 13 offers an important new option for adults 50 years and older to include as part of their preventive strategy for healthy aging.”

In addition to the United States, Pfizer has been granted approval for use of Prevnar 13 for various indications in adults 50 years of age and older in the European Union, Australia, Mexico and more than 10 other countries. Prevnar 13 was first approved by the U.S. FDA in February 2010 for the prevention of invasive pneumococcal disease in infants and young children from 6 weeks through 5 years of age.

About Prevnar 13 and Conjugate Technology

Prevnar 13 uses Company-pioneered conjugate technology that links pneumococcal polysaccharide sugar chains found on the surface of each bacterial serotype with a carrier protein. Prevnar 13 uses the carrier protein CRM_{197}, which has more than 20 years of clinical and commercial use in vaccines.

Pneumococcal Disease

Pneumococcal disease is a group of infections caused by the bacterium *Streptococcus pneumoniae*, also known as pneumococcus. The most common manifestation of PD in adults 50 years of age and older is non-bacteremic pneumococcal pneumonia, a non-invasive form of the disease. PD also causes invasive infections, such as bacteremia and meningitis, in adults.

Indication for Prevnar 13 for Adults 50 Years of Age and Older

- In adults 50 years of age and older, Prevnar 13 is indicated for active immunization for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F
- This indication is based on immune responses elicited by Prevnar 13. There have been no controlled trials in adults demonstrating a decrease in invasive pneumococcal disease or pneumococcal pneumonia after vaccination with Prevnar 13
- Prevnar 13 will not protect against disease caused by *Streptococcus pneumoniae* serotypes that are not in the vaccine
- The effectiveness of Prevnar 13 administered less than five years after pneumococcal polysaccharide vaccine is not known

Indication for Prevnar 13 for Children 6 Weeks through 5 Years of Age

- In children 6 weeks through 5 years of age (prior to the 6th birthday), Prevnar 13 is indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F
- Prevnar 13 will not protect against disease caused by *Streptococcus pneumoniae* serotypes that are not in the vaccine

Important Safety Information for Prevnar 13

- Severe allergic reaction (e.g., anaphylaxis) to any component of Prevnar 13, Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]), or any diphtheria toxoid–containing vaccine is a contraindication to the use of Prevnar 13
- Prevnar 13 does not provide 100% protection against vaccine serotypes or protect against nonvaccine serotypes
- Immunocompromised children and adults or those with impaired immune responsiveness due to the use of immunosuppressive therapy may have a reduced antibody response to active immunization
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including Prevnar 13, to infants born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination
- In pediatric clinical trials, the most commonly reported serious adverse events were bronchiolitis (0.9%, 1.1%), gastroenteritis (0.9%, 0.9%), and pneumonia (0.9%, 0.5%) for Prevnar 13 and Prevnar, respectively
- In infants and toddlers vaccinated at 2, 4, 6, and 12-15 months of age in U.S. clinical trials, the most commonly reported solicited adverse reactions were irritability (>70%), injection site tenderness (>50%), decreased appetite (>40%), decreased sleep (>40%), increased sleep (>40%), fever (>20%), injection site redness (>20%), and injection site swelling (>20%)
- In adults aged 50 years and older the commonly reported solicited adverse reactions were pain at the injection site (>50%), fatigue (>30%), headache (>20%), muscle pain (>20%), joint pain (>10%), decreased appetite (>10%), injection site redness (>10%), injection site swelling (>10%), limitation of arm movement (>10%), chills (>5%) or rash (>5%)

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of December 30, 2011. 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 the CAPiTA trial currently being conducted as well as the trial that will be conducted to evaluate concomitant use of Prevnar 13 and TIV in adults 50 years of age and older who have been previously immunized with PPSV. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including uncertainty regarding the results of the two trials and their impact on the commercial potential of the indication or indications for Prevnar 13/Prevenar 13 approved in the U.S. and various other countries for adults 50 years of age and older; 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, 2010 and in its reports on Form 10-Q and Form 8-K.

*Prevnar 13 is referred to as Prevenar 13 in most countries outside the United States.

Pfizer Inc. Media: Victoria Davis, 484-865-5194 / 347-558-3455 (cell) or Investors: Suzanne Harnett, 212-733-8009