Pfizer Receives FDA Approval For The Use Of Prevnar 13 In Vaccine-Naive Children And Adolescents Aged 6 Years Through 17 Years For The Prevention Of Invasive Pneumococcal Disease

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Prevnar 13 is the First and Only Pneumococcal Conjugate Vaccine Approved for This Age Group

"As a global leader in pneumococcal disease prevention, extending the impact of Prevnar 13 to older children and adolescents aged 6 through 17 years is a reflection of our dedication to improving public health worldwide"

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has granted approval for the expansion of the company’s pneumococcal conjugate vaccine, Prevnar 13®* (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), for use in older children and adolescents aged 6 years through 17 years for active immunization for the prevention of invasive disease caused by the 13 Streptococcus pneumoniae serotypes contained in the vaccine. For this age group, Prevnar 13 is administered as a one-time dose to patients who have never received Prevnar 13.1

“As a global leader in pneumococcal disease prevention, extending the impact of Prevnar 13 to older children and adolescents aged 6 through 17 years is a reflection of our dedication to improving public health worldwide,” said Susan Silbermann, president, vaccines, Pfizer. “We continue to work tirelessly to make this vaccine available to people at risk for invasive pneumococcal disease.”

The FDA approval followed submission and review of a Phase 3, open-label trial of Prevnar 13 in 592 older children and adolescents, including those with asthma.2 The study met all endpoints, demonstrating immunogenicity and establishing a safety profile in children aged 6 years through 17 years consistent with the safety profile established in previous trials in infants and young children.2

About Prevnar 13

Prevnar 13 was first introduced for use in infants and young children in December 2009 in Europe and in February 2010 in the U.S., and it is now approved for such use in nearly 120 countries worldwide. It is the most widely used pneumococcal conjugate vaccine in the world, and more than 500 million doses of Prevnar/Prevnar 13 have been distributed worldwide. Currently, Prevnar 13 is included as part of a national or regional immunization program in more than 60 countries, offering coverage against invasive pneumococcal disease to nearly 30 million children per year.3

Prevnar 13 is also approved for use in adults 50 years of age and older in more than 80 countries and it is the first and only pneumococcal vaccine to be granted World Health Organization prequalification in the adult population.3

About Pneumococcal Disease

Pneumococcal disease (PD) is a group of illnesses caused by the bacterium Streptococcus pneumoniae (S. pneumoniae), also known as pneumococcus.4 PD is associated with significant morbidity and mortality.4 Invasive manifestations of the disease include bacteremia (bacteria in the blood) and meningitis (infection of the tissues surrounding the brain and spinal cord).4 Invasive pneumococcal disease can affect people of all ages, although older adults and young children are at heightened risk.4,5,6

U.S. Indication for Prevnar 13

Prevnar 13 is a vaccine approved for the prevention of invasive disease caused by 13 S. pneumoniae strains (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in children 6 weeks through 17 years of age, and in children 6 weeks through 5 years for the prevention of otitis media caused by 7 of the 13 strains (4, 6B, 9V, 14, 18C, 19F, and 23F)

Based upon immune responses to the vaccine, Prevnar 13 is also approved for adults 50 years of age and older for the prevention of pneumococcal pneumonia and invasive disease caused by the 13 vaccine 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 (e.g., HIV infection, leukemia) may have a reduced immune response A temporary pause of breathing following vaccination has been observed in some infants born prematurely The most commonly reported serious adverse events in children were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%) In infants and toddlers, the most common side effects were tenderness, redness or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever 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 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 your child
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 January 25, 2013. 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 potential indications for Prevnar 13/Prevenar 13 in age groups for which it has not received regulatory approval in various jurisdictions. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities in jurisdictions in which applications have been or may be filed for such potential indications regarding whether and when to approve such applications, as well as their decisions regarding labelling and other matters that could affect the availability and commercial potential of such indications; 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, 2011, and in its reports on Form 10-Q and Form 8-K.

References

Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) DRAFT Prescribing Information, Wyeth Pharmaceuticals Inc. Data on File (DOF). 13vPnC-Infant Clinical Study Report. Final Report For Groups 3 And 4: A Phase 3, Open Label Trial Evaluating The Safety, Tolerability, And Immunogenicity Of 13 Valent Pneumococcal Conjugate Vaccine In Healthy Children Aged 15 Months To 17 Years In The United States. Pfizer Data on File (DOF). World Health Organization (WHO). 23-valent pneumococcal polysaccharide vaccine. WHO Position Paper. Wkly Epidemiol Rec. 2008;83(42):373-384. Centers for Disease Control and Prevention. Updated recommendations for prevention of invasive pneumococcal disease among adults using the 23-valent pneumococcal polysaccharide vaccine (PPSV23). MMWR. 2010;59(34):1102-1106. Centers for Disease Control and Prevention. Prevention of pneumococcal disease among infants and children – use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). 2010;59(RR-11):1-19.
*Prevnar 13 is referred to as Prevenar 13 in most countries outside the United States.

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