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Pfizer Receives FDA Approval for Prevnar 13® in Adults Age 18 Through 49

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Prevnar 13 is the only pneumococcal vaccine approved in the U.S. for patients 6 weeks through adulthood

“Forward-Looking Information and Factors That May Affect Future Results”

Pfizer Inc. (NYSE:PFE) today announced that Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) received U.S. Food and Drug Administration (FDA) approval for an expanded age indication to include adults 18 through 49 years of age, in addition to the already approved indication for adults 50 years and older, for active immunization for the prevention of pneumonia and invasive disease caused by 13 *Streptococcus pneumoniae (S. pneumoniae)* serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). Prevnar 13 is the only pneumococcal vaccine approved across the lifespan.

With today’s decision Prevnar 13 is approved for:

- Adults 18 years of age and older for the prevention of pneumococcal pneumonia and invasive disease caused by 13 *Streptococcus pneumoniae* strains in the vaccine
- Children 6 weeks through 17 years of age (prior to the 18th birthday) for the prevention of invasive disease caused by 13 *Streptococcus pneumoniae* strains in the vaccin

The expanded age indication now more closely aligns with the 2012 U.S. Centers for Disease Control and Prevention’s Advisory Committee on Immunizations Practices (ACIP) recommendations for adults 19 years of age and older with immunocompromising conditions (e.g., HIV, chronic renal failure, cancer), functional or anatomic asplenia (e.g., sickle cell disease), cerebral spinal fluid leak, and Cochlear implants. This is in addition to recommendations set forth by ACIP in 2014 for adults 65 years and older.

“This expanded age indication in adults 18 to 49 offers an important public health benefit as appropriate vaccination against *S. pneumoniae* is critical to reducing the risk of pneumococcal disease, including in those with immunocompromising conditions," said Dr. Luis Jodar, Chief Medical and Scientific Affairs Officer, Pfizer Vaccines.

The FDA’s decision to approve the label expansion followed the submission and review of data from an open-label, Phase 3 trial of Prevnar 13 in adults who were not previously vaccinated with the 23-valent pneumococcal polysaccharide vaccine (PPSV23).[1] The study, which was published in *Vaccine* in October 2015, compared the immunogenicity, safety, and tolerability of Prevnar 13 in adults age 18 to 49 years with adults age 60 to 64, for whom Prevnar 13 was already approved.

S. pneumoniae, also known as pneumococcus, is the most common bacterial cause of community-acquired pneumonia.[2] 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.[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®* (pneumococcal polysaccharide conjugate vaccine [13 – valent, adsorbed]) was first approved in the European Union (EU) in December 2009 for use in infants and young children. Prevenar 13 is the most widely used pneumococcal conjugate vaccine in the world, and is included in the pediatric National Immunization Programs in 102 countries. It is approved in the United States, 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 now approved in the U.S., the EU and 44 other countries for use in adults 18 to 49 years of age.

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

U.S. INDICATIONS FOR PREVNAR 13®

- Prevnar 13® is a vaccine approved for adults 18 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)
- In children 6 weeks through 17 years of age (prior to the 18th birthday), Prevnar 13® is indicated for the prevention of invasive disease caused by *S pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F
- In children 6 weeks through 5 years of age (prior to the 6th birthday), Prevnar 13® is indicated for the prevention of otitis media caused by *S pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F
- Prevnar 13® is not 100% effective and will only help protect against the 13 strains included in the vaccine

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, vomiting, 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 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://www.pfizer.com/products/product-detail/prevnar_13.

Pfizer Inc: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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 one of the world's premier innovative biopharmaceutical companies, we 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. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of July 12, 2016. 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 expanded age indication for Prevnar 13 in the U.S.; uncertainty concerning whether and when regulatory authorities in various other jurisdictions will update the label and whether and when vaccine technical committees in various other jurisdictions 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 Prevnar 13/Prevenar 13 for the prevention of pneumococcal pneumonia in adults caused by the 13 serotypes in Prevnar 13/Prevenar 13, and whether and when regulatory authorities in jurisdictions where such applications are pending or submitted will approve any such submissions, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; 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, 2015 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] Bryant K.A., Frenck R., Gurtmanc A., et. al. Immunogenicity and safety of a 13-valent pneumococcal conjugate vaccine in adults 18–49 years of age, naive to 23-valent pneumococcal polysaccharide vaccine. *Vaccine*. 2015;33:5854–5860.

[2] Centers for Disease Control and Prevention. Pneumonia can be prevented - vaccines can help. http://www.cdc.gov/features/pneumonia/. Accessed January 23, 2013.

[3] 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.

[4] World Health Organization. Immunization, vaccines and biologicals. Pneumococcal vaccines. http://archives.who.int/vaccines/en/pneumococcus.html. Accessed October 20, 2014.

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