

Pfizer Receives European Approval To Expand Use Of Prevenar 13* To Adults Aged 18 To 49 Years For The Prevention Of Invasive Pneumococcal Disease

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NEW YORK, N.Y., July 10 – Pfizer Inc. (NYSE: PFE) announced today the company’s pneumococcal conjugate vaccine, Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]), received European approval for an expanded indication to include adults aged 18 to 49 years for active immunization for the prevention of invasive disease caused by vaccine-type *Streptococcus pneumoniae* (*S. pneumoniae*).¹ Previously approved in the European Union (EU) for use in infants, young children and adolescents aged 6 weeks to 17 years, as well as adults 50 years of age and older, Prevenar 13 is now the only pneumococcal vaccine in the EU that offers protection against invasive disease from infancy through adulthood.¹ The European Commission is the first to approve Prevenar 13 to offer protection against invasive disease at all stages of life.

“Prevenar 13 has been administered to millions of individuals around the world, and today’s European approval for the expanded use of Prevenar 13 is a testament to Pfizer’s continued commitment to developing innovative vaccines that can help prevent serious – and sometimes fatal – disease through every stage of life,” said Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer.

The European Commission’s decision to approve this label expansion for Prevenar 13 followed the submission and review of data from an open-label Phase 3 trial of the vaccine in healthy adults aged 18 to 49 years.² The study – which met all primary and secondary objectives – showed that Prevenar 13 is at least as immunogenic in this age group as it is in adults 60 to 64 years of age, as measured one month after vaccination.² Furthermore, Prevenar 13 showed a favorable safety profile and was generally well tolerated.²

“Adults aged 18 to 49 years with certain underlying medical conditions may benefit in particular from vaccination with Prevenar 13 because of an increased risk of pneumococcal disease,” said Luis Jodar, Ph.D., vice president, Vaccines Global Medicines Development Group, Pfizer. “Pfizer will continue to partner with health authorities worldwide to seek to provide access to this important vaccine to all those at risk of the disease.”

Prevenar 13, or Pevnar 13 as it is called in the United States, Canada and Taiwan, was first introduced for use in infants and young children in December 2009 in the EU. It is now approved in more than 120 countries worldwide for use in infants and young children, and in more than 80 countries for use in adults 50 years of age and older.

Pneumococcal Disease (PD)

Pneumococcal Disease is a group of illnesses caused by the bacterium *S. pneumoniae*, also known as pneumococcus.³ It can affect people of all ages, although older adults, young children and individuals with certain chronic medical conditions are at heightened risk.^{4,5} PD is associated with significant morbidity and mortality.^{4,5} Invasive manifestations of the disease include bacteremia (bacteria in the blood) and meningitis (infection of the tissues surrounding the brain and spinal cord).^{3,6}

Indication for Prevenar 13 in Europe

Prevenar 13 is approved in the EU for the prevention of invasive disease, pneumonia and acute otitis media caused by *S. pneumoniae* serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in children and adolescents aged 6 weeks to 17 years.¹ It is also approved in the EU for the prevention of invasive disease caused by 13 *S. pneumoniae* serotypes (single dose) in adults 18 years of age and older. For the full prescribing information for Prevenar 13 in the EU, please see the Summary of Product Characteristics.

Indication for Prevnar 13 in the United States

- Prevnar 13 is a vaccine approved for children 6 weeks through 17 years of age 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), and for 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)⁷
- 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 strains⁷
- Prevnar 13 is not 100% effective and will only help protect against the 13 strains included in the vaccine⁷
- Effectiveness when given less than 5 years after a pneumococcal polysaccharide vaccine is not known⁷

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 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. Most commonly reported side effects in children 5 years through 17 years also included hives
- 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 you or your child

For the full prescribing information for Prevnar 13, please click here

http://www.pfizer.com/products/rx/rx_product_prevnar13.jsp.

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

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