Pfizer Receives European Approval To Expand Use Of Prevenar 13 To Older Children And Adolescents Aged 6 To 17 Years For The Prevention Of Pneumococcal Disease

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

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--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the European Commission has approved expanding the use of the company's pneumococcal conjugate vaccine, Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]), to older children and adolescents aged 6 to 17 years for active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by vaccine-type Streptococcus pneumoniae. Children in this age group who have not previously received Prevenar 13 may receive a single dose of the vaccine.

"Prevenar 13 has been administered to millions of infants and young children around the world and helps protect against the often fatal effects of pneumococcal disease," said Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer. "As the global leader in pneumococcal disease prevention, Pfizer continues to study the use of this life-saving vaccine across all ages."

The European Commission's decision to approve this expanded indication followed submission and review of a Phase 3, open-label trial of Prevenar 13 in 592 healthy children and adolescents, including those with underlying medical conditions such as asthma (17.4% of the study population). The study met all endpoints, demonstrating immunogenicity and establishing a safety profile in children and adolescents aged 6 to 17 years consistent with the safety profile established in previous trials in infants and young children.

"Children and adolescents aged 6 to 17 with underlying medical conditions have an increased risk of pneumococcal disease," said Luis Jodar, Ph.D., vice president, Vaccines Global Medicines Development Group, Pfizer. "Pfizer will continue working with health authorities worldwide in an effort to provide access to Prevenar 13 to those at risk of disease."

About Prevenar 13

Prevenar 13 was first introduced for use in infants and young children in December 2009 in Europe and is now approved for such use in more than 120 countries worldwide. It is the most widely used pneumococcal conjugate vaccine, with more than 500 million doses of Prevenar/Prevenar 13 having been distributed worldwide. Currently, Prevenar 13 is included as part of a national or regional immunization program in more than 60 countries, helping to protect more than 30 million children per year against invasive pneumococcal disease.

Prevenar 13 offers the broadest serotype coverage of any currently available pneumococcal conjugate vaccine for prevention of pneumococcal disease including invasive pneumococcal disease, pneumonia and otitis media. The 13 pneumococcal serotypes in Prevenar 13 (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) are among the most prevalent invasive-disease-causing strains in children worldwide.

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

Prevenar 13 is marketed in the United States as Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]). In the United States, Prevnar 13 is not indicated for the prevention of pneumococcal pneumonia in the pediatric population.

Pneumococcal Disease

Pneumococcal Disease (PD) is a group of illnesses caused by the bacterium Streptococcus pneumoniae (S. pneumoniae), also known as pneumococcus. While pneumococcus can infect people of all ages, infants, and young children and individuals with certain underlying chronic conditions, are at heightened risk. Certain underlying medical conditions, such as asthma and illnesses that impact a person's immune system, can increase an individual's risk of PD. PD is associated with significant morbidity and mortality.

Indication for Prevenar 13 in Europe

Prevenar 13 is approved in the EU for active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by vaccine-type S. pneumoniae in infants and children from 6 weeks to 17 years of age and invasive pneumococcal disease in adults aged 50 years and older.

Important Safety Information for Prevenar 13

The use of Prevenar 13 should be determined on the basis of official recommendations taking into consideration the impact of invasive disease in different age groups as well as the variability of serotype epidemiology in different geographical areas.

In clinical studies, the most commonly reported adverse reactions were injection-site reactions, fever, irritability, decreased appetite, and increased and/or decreased sleep.

Risks are associated with all vaccines, including Prevenar 13. Hypersensitivity to any component, including diphtheria toxoid, is a contraindication to its use. As with other vaccines, the administration of Prevenar 13 should be postponed in subjects suffering from acute, severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination. Prevenar 13 does not provide 100 percent protection against vaccine serotypes or protect against non-vaccine serotypes.

Indications for Prevnar 13 in the United States

In the United States, Prevnar 13 is indicated for use in children six weeks through 5 years of age for the prevention of invasive disease (e.g., meningitis, bacteremia) caused by 13 Streptococcus pneumoniae serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). The vaccine is also indicated in adults 50 years of age and older for active immunization for the prevention of pneumonia and invasive disease caused by the 13 Streptococcus pneumoniae serotypes contained in the vaccine (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F). Indication is based on immune responses.

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DISCLOSURE NOTICE: The information contained in this release is as of January 8, 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 labeling 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.

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