# CDC’s Advisory Committee On Immunization Practices Recommends Pfizer’s Prevnar 13™ Vaccine For The Prevention Of Invasive Pneumococcal Disease In Infants And Young Children In The U.S.

Wednesday, February 24, 2010 - 03:03am

Recommendations Include Primary Dosing Series and a Supplemental Dose for Children Fully Immunized with Prevnar

(BUSINESS WIRE)--Pfizer Inc (NYSE:PFE) announced today that the United States Centers for Disease Control and Prevention's (CDC’s) Advisory Committee on Immunization Practices (ACIP) has recommended the use of Prevnar 13™ (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) for healthy children aged 2 months through 59 months for the prevention of invasive pneumococcal disease caused by the 13 pneumococcal serotypes included in the vaccine.

The ACIP's recommendations include the routine use of Prevnar 13 for infants and toddlers, as well as a supplemental dose for children through 59 months of age who have completed the 4-dose immunization series with Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein]). In addition, the ACIP recommended that children who have started their immunization series with Prevnar should complete the series by switching to Prevnar 13 at any point in the schedule.

Prevnar 13 includes the seven serotypes (4, 6B, 9V, 14, 18C, 19F, and 23F) in Prevnar – available in the United States since 2000 – plus six additional serotypes (1, 3, 5, 6A, 7F, and 19A). Together, these 13 serotypes are responsible for the majority of remaining invasive pneumococcal disease in infants and young children in the United States. In particular, serotype 19A is now the most common cause of invasive pneumococcal disease among children younger than 5 years of age in the United States.

“We are pleased that the Advisory Committee has recommended the use of Prevnar 13, with coverage for 13 important invasive disease-causing serotypes, in infants and young children in the United States,” says Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer Inc. “The incidence of disease caused by serotypes not included in Prevnar has been increasing in children younger than 5 years of age in the United States, including 19A , the most common serotype.”

The ACIP’s recommendations for Prevnar 13 vaccination of healthy unimmunized children 2 months through 59 months of age are identical to those previously recommended by ACIP for Prevnar, with Prevnar 13 replacing Prevnar for all doses.

Highlights of the ACIP recommendations included the following:

Prevnar 13 is administered as a 4-dose series at 2, 4, 6 and 12 through 15 months of age. Children who have begun their vaccination series with Prevnar should complete the series by switching to Prevnar 13 at any point in the schedule. A single supplemental dose of Prevnar 13 is recommended for children through 59 months of age who have completed the 4-dose immunization series with Prevnar.
Earlier today, the United States Food and Drug Administration (FDA) approved Prevnar 13 for active immunization of children 6 weeks through 5 years of age for the prevention of 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 also indicated for the prevention of otitis media caused by serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F. No otitis media efficacy data are available for serotypes 1, 3, 5, 6A, 7F, and 19A.

In the United States, the Prevnar 13 product label recommends a 4-dose series at 2, 4, 6, and 12 to 15 months of age. Children who have received one or more doses of Prevnar may complete the 4-dose immunization series with Prevnar 13. Additionally, children 15 months through 5 years of age who have received four doses of Prevnar may receive one dose of Prevnar 13 to elicit immune responses to the six additional serotypes. The immune responses induced by this Prevnar 13 transition schedule may result in lower antibody concentrations for the six additional serotypes (types 1, 3, 5, 6A, 7F, and 19A),

compared to antibody concentrations following four doses of Prevnar 13 (given at 2, 4, 6, and 12 to 15 months). The clinical relevance of these lower antibody responses is not known.

Pfizer expects Prevnar 13 to be introduced commercially in the United States in the first quarter of 2010. In addition to the approval of Prevnar 13 in the United States, Prevenar 13* (Pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]), as it is known in most countries outside the United States, has been approved for use in infants and young children in 38 other countries. Further regulatory filings for Prevnar 13 for pediatric use are in advanced stages of review in various countries spanning six continents. Prevnar 13 is also being studied in global Phase III clinical trials in adults, with regulatory submissions expected later this year.

Pneumococcal Disease

According to a World Health Organization (WHO) 2002 estimate, pneumococcal disease is the leading cause of vaccine-preventable death worldwide in children younger than 5 years. Pneumococcal disease is complex and describes a group of illnesses, all caused by the bacterium S. pneumoniae. It affects infants and young children and includes invasive infections such as bacteremia/ sepsis and meningitis, as well as non-invasive disease including acute otitis media.

Indication for Prevnar 13

Prevnar 13 is a vaccine approved for use 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 13 strains of Streptococcus pneumoniae (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F).

Prevnar 13 is also indicated for the prevention of otitis media (ear infection) caused by 7 strains of Streptococcus pneumoniae (4, 6B, 9V, 14, 18C, 19F, and 23F). No efficacy data for ear infections are available for strains 1, 3, 5, 6A, 7F, and 19A.

Important Safety Information for Prevnar 13

Prevnar 13 should not be given to anyone with a severe allergic reaction to any component of Prevnar 13, Prevnar or any diphtheria toxoid-containing vaccine.

Prevnar 13 may not protect all individuals receiving the vaccine. Protection against ear infections is expected to be less than that for invasive disease. Children with weakened immune systems may have a reduced immune response to Prevnar 13. A temporary pause of breathing following vaccination has been observed in some infants born prematurely.

The most common side effects are redness, swelling and tenderness at the injection site, fever, decreased appetite, irritability, increased sleep, and decreased sleep. Any side effects associated with the vaccination should be reported to your child’s health care provider.

Indication for Prevnar

Prevnar is indicated for active immunization of infants and toddlers against serious invasive disease caused by S. pneumoniae, including bacteremia (bloodstream infection) and meningitis (infection of the membranes surrounding the brain and spinal cord) caused by the seven serotypes in the vaccine. The seven serotypes (strains) of S. pneumoniae included in the vaccine (4, 6B, 9V, 14, 18C, 19F, and 23F) were the strains that most commonly caused these serious diseases in children prior to the introduction of the vaccine. The routine schedule is 2, 4, 6, and 12-15 months of age.

Prevnar is also indicated for immunization of infants and toddlers against otitis media (ear infections) caused by the seven serotypes in the vaccine. Protection against ear infections is expected to be less than that for invasive disease.

As with any vaccine, Prevnar may not protect all individuals receiving the vaccine from serious invasive disease caused by S. pneumoniae. This vaccine should not be used for treatment of active infection.

Important Safety Information for Prevnar

In clinical studies, the most frequently reported adverse events included injection site reactions, fever (≥38ºC/100.4ºF), irritability, drowsiness, restless sleep, decreased appetite, vomiting, diarrhea, and rash.

Risks are associated with all vaccines, including Prevnar. Hypersensitivity to any vaccine component, including diphtheria toxoid, is a contraindication to its use. Prevnar does not protect 100 percent of children vaccinated. Immunization with Prevnar does not substitute for routine diphtheria immunization.

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 February 24, 2010. 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 a potential indication for Prevnar 13 for use in infants and young children in the various countries in which the Company's regulatory applications are pending; when Prevnar 13 is expected to be introduced commercially in the U.S. for that indication; the anticipated submission of regulatory applications in various countries in 2010 for a potential indication for Prevnar 13 for use in adults; and the potential benefits of Prevnar 13. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when regulatory applications will be submitted in various countries for a potential indication for Prevnar 13 for use in adults; whether and when the regulatory authorities in various jurisdictions will approve applications that have been or may be submitted for these potential indications and their decisions regarding labeling and other matters that could affect the availability or commercial potential of these 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, 2008 and in its reports on Form 10-Q and Form 8-K.

* Trademark

Media: Gwen Fisher, +1-484-865-5160 Investor: Suzanne Harnett, +1-212-733-8009