Pfizer Receives FDA Approval for Prevnar 13™ for the Prevention of Invasive Pneumococcal Disease in Infants and Young Children

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(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that the United States Food and Drug Administration (FDA) has granted approval for Prevnar 13™ (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), the Company's 13-valent pneumococcal conjugate vaccine. Prevnar 13 is indicated 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.

Invasive pneumococcal disease includes sepsis and bacteremia (bloodstream infections), meningitis (inflammation of the coverings of the brain and spinal cord), bacteremic pneumonia, and empyema (accumulation of pus in the cavity surrounding the lungs).

"The approval of Prevnar 13 means that infants and young children in the United States will have access to a pneumococcal conjugate vaccine that provides coverage against 13 serotypes that could potentially result in life-threatening illnesses," says Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer Inc. "Together, these 13 serotypes are responsible for the majority of invasive pneumococcal disease in the United States. Notably, serotype 19A is now the most common invasive disease-causing serotype in young children."

Prevnar 13 includes the seven serotypes (4, 6B, 9V, 14, 18C, 19F, and 23F) in Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) – the first pneumococcal conjugate vaccine introduced in 2000 – plus six additional serotypes (1, 3, 5, 6A, 7F, and 19A).

“While the incidence of invasive pneumococcal disease caused by the serotypes in Prevnar has been substantially reduced since the introduction of the vaccine in 2000, invasive pneumococcal disease remains a serious health threat to infants and young children,” adds Dr. Emini.

In connection with the approval by the FDA, the Company has agreed to certain post-marketing commitments involving conducting a study to further evaluate the safety profile of Prevnar 13, a study to evaluate the prevention of overall invasive pneumococcal disease and various studies to evaluate reduction in otitis media. The approval of Prevnar 13 is based on the review of 13 Phase III studies involving more than 7,000 infants and young children. Data from the Phase III trials support the safety and efficacy of Prevnar 13 for the prevention of invasive pneumococcal disease in infants and young children. Clinical trial data indicate that Prevnar 13 can be administered with all routine pediatric vaccines studied.

Prevnar 13 is recommended to be administered as 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. 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.

“This approval is a significant milestone for Pfizer and yet another expression of our mission to improve health and well-being at every stage of life,” says Geno Germano, president and general manager, Specialty Care Business Unit, Pfizer Inc. “Prevnar 13 is an important priority for the entire Pfizer organization as we continue to expand our presence in the vaccine category.”

Prevnar 13 will be discussed today at the upcoming meeting of the Advisory Committee on Immunization Practices (ACIP) and the Company expects the vaccine to be introduced commercially in the United States in the first quarter of this year. In addition to its

approval 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. 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 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 Streptococcus 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.

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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.

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