Prevenar 13 to provide the broadest coverage of any pneumococcal conjugate vaccine for infants and young children

Thursday, December 10, 2009 - 07:22pm

Prevenar 13 to provide the broadest coverage of any pneumococcal conjugate vaccine for infants and young children

(BUSINESS WIRE)--The European Commission has granted Pfizer Inc. (NYSE: PFE) a European marketing authorization for its pneumococcal conjugate vaccine, Prevenar 13* (Pneumococcal Polysaccharide Conjugate Vaccine [13-valent, adsorbed]). Prevenar 13 is indicated for active immunization for the prevention of invasive disease, pneumonia, and acute otitis media caused by 13 Streptococcus pneumoniae serotypes in infants and children from 6 weeks to 5 years of age. Invasive pneumococcal disease includes sepsis, meningitis, bacteremia, bacteremic pneumonia, and empyema.

Prevenar 13, built on the scientific foundation of Prevenar* (Pneumococcal Saccharide Conjugated Vaccine, Adsorbed), provides the broadest serotype coverage of any pneumococcal conjugate vaccine. It includes the seven serotypes (4, 6B, 9V, 14, 18C, 19F, and 23F) in Prevenar – the standard in pneumococcal disease prevention in infants and young children – plus six additional serotypes (1, 3, 5, 6A, 7F, and 19A), which together represent the most prevalent invasive disease-causing strains in young children worldwide. Prevenar 13 is the only pneumococcal conjugate vaccine to include serotypes 3, 6A, and 19A. Both Prevenar and Prevenar 13 use CRM – a carrier protein which has been used in various approved pediatric conjugate vaccines for more than 20 years. Available in Europe since 2001, Prevenar is currently available in more than 100 countries and more than 300 million doses have been distributed worldwide.

“Although the incidence of pneumococcal disease has been significantly reduced in European countries and elsewhere where Prevenar is routinely used, pneumococcal disease remains a serious threat to children in Europe as strains such as serotypes 19A and 6A are increasing in prevalence and frequently resistant to antibiotics,” says Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer Inc. “By providing the broadest serotype coverage of any pneumococcal conjugate vaccine, Prevenar 13 is poised to help reduce the serious public health risk and economic burden associated with pneumococcal disease.”

The European Commission’s authorization of Prevenar 13 was based on a clinical trial program of 13 core Phase III studies involving more than 7,000 children. Data from the Phase III trials support the safety and efficacy of Prevenar 13 for the prevention of pneumococcal disease in infants and young children. Clinical trial data indicate Prevenar 13 has a safety profile similar to that of Prevenar, and can be administered with all routine pediatric vaccines studied.

In the European marketing authorization, the schedule recommended for Prevenar 13 consists of four doses, three primary doses, followed by a booster dose between 11 and 15 months of age. Alternatively, when Prevenar 13 is given as part of a routine infant immunization program, Prevenar 13 may be administered as a three dose series, two primary doses followed by a booster dose. Infants and children who have begun immunization with Prevenar may switch to Prevenar 13 at any point in their dosing schedule. It is also recommended that children up to 5 years of age who have completed vaccination with Prevenar should be offered coverage against the six additional serotypes included in Prevenar 13. The number of doses of Prevenar 13 required to complete immunization should follow official recommendations in each member state. It is recommended that infants who receive a first dose of Prevenar 13 complete the vaccination course with Prevenar 13.

“Prevenar 13, with serotype coverage unmatched by any other pneumococcal conjugate vaccine, is an excellent example of Pfizer’s innovative vaccine technology at work,” says Geno Germano, president and general manager, Specialty Care Business Unit, Pfizer Inc. “We are committed to vaccines as a key part of our growth strategy, which is an expression of our mission to improve health and well-being at every stage of life.”

To date, Prevenar 13 has been approved for use in infants and young children in 3 countries. On November 18, 2009, the United States Food and Drug Administration’s (FDA) Vaccines and Related Biological Products Advisory Committee voted 10 to 1 that the data presented from the Biologic License Application (BLA) for Prevnar 13™

(Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), as the vaccine is known in the United States, support its safety and efficacy for the prevention of invasive pneumococcal disease in infants and young children. The FDA will consider the Advisory Committee's votes and discussion in its review of the Prevnar 13 BLA, which has an action date of December 30, 2009. Other pediatric regulatory filings for Prevnar 13 are in advanced stages of review in various countries spanning six continents. Prevenar 13 is also being studied in global Phase III clinical trials in adults, with regulatory submissions expected in 2010.

Pneumococcal Disease

According to a World Health Organization (WHO) 2002 estimate, pneumococcal disease is a 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 Streptococcus pneumoniae. Pneumococcal disease affects both children and adults, and includes invasive infections such as bacteremia/sepsis and meningitis, as well as pneumonia and acute otitis media.

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% protection against vaccine serotypes or protect against non-vaccine serotypes.

Indication for Prevenar

Prevenar is indicated for active immunization of infants and children from 6 weeks through 9 years of age against invasive disease, pneumonia, and otitis media caused by Streptococcus pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F.

Important Safety Information for Prevenar

In clinical studies (n=18,168), 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 Prevenar. Hypersensitivity to any vaccine component, including diphtheria toxoid, is a contraindication to its use. Prevenar does not provide 100% protection against vaccine serotypes or protect against nonvaccine serotypes. The decision to administer Prevenar* should be based on its efficacy in preventing invasive pneumococcal disease.

The frequency of pneumococcal serotypes and serogroups can vary from country to country, which could influence the effectiveness of the vaccine in any given country.

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 December 11, 2009. 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 Prevenar 13* for use in infants and young children in the various countries in which the Company's regulatory applications are pending, including the U.S.; the anticipated submission of regulatory applications in various countries in 2010 for a potential indication for Prevenar 13* for use in adults; and the potential benefits of Prevenar 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 Prevenar 13 for use in adults; whether and when the FDA and regulatory authorities in other 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.

Pfizer Inc.Media:Gwen Fisher, +1-484-865-5160orInvestors:Jennifer M. Davis, +1-212-733-0717