FDA Advisory Committee Finds Data Support the Safety and Effectiveness of Prevnar 13™ Vaccine for the Prevention of Invasive Pneumococcal Disease in Infants and Young Children

Wednesday, November 18, 2009 - 03:39am

(BUSINESS WIRE)--Pfizer Inc (NYSE:PFE) announced today that the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee voted 10 to 1 that the data presented support the safety and effectiveness of its 13-valent pneumococcal conjugate candidate vaccine, Prevnar 13™ (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), for the prevention of invasive pneumococcal disease in infants and young children. The Company is seeking an indication for active immunization of infants and toddlers for the prevention of invasive disease (including sepsis, meningitis, bacteremia, bacteremic pneumonia, and empyema) and otitis media caused by 13 Streptococcus pneumoniae (S. pneumoniae) serotypes. The FDA will consider the Advisory Committee's votes and discussion in its review of the Biologic License Application (BLA) for Prevnar 13, which has an action date of December 30, 2009.

Prevnar 13 includes the seven serotypes (4, 6B, 9V, 14, 18C, 19F, and 23F) in Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), plus six additional serotypes (1, 3, 5, 6A, 7F, and 19A) associated with the majority of remaining invasive pneumococcal disease in infants and young children in the U.S. Serotype 19A is

the most common serotype in the U.S. Prevnar®, the standard in pneumococcal disease prevention for infants and young children, was first introduced in the U.S. in 2000.

“Pfizer is very pleased with the outcome of the Advisory Committee’s votes on the safety and effectiveness of Prevnar 13,” says Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer Inc. “We look forward to working with the FDA to obtain approval for this important vaccine.”

The Advisory Committee’s votes in support of Prevnar 13™ were based on a review of the data from 13 core Phase III studies involving more than 7,000 children. The Advisory Committee’s discussion included consideration of the multiple immunogenicity endpoints in the trials. The Committee agreed that the totality of the data supported the effectiveness of Prevnar 13 for the prevention of invasive pneumococcal disease in infants and young children. The Committee also discussed the Prevnar 13 safety profile and agreed that the data were adequate to support its safety. In clinical studies, the most commonly reported adverse events for Prevnar 13 included injection site reactions, irritability, drowsiness/increased sleep, decreased appetite, fever, and restless sleep/decreased sleep.

"Prevnar 13 demonstrates Pfizer’s commitment to vaccine innovation – a key strategic priority for Pfizer and an expression of its vision to broaden and diversify its global product portfolio," says Geno Germano, president and general manager, Specialty Care Business Unit, Pfizer Inc. "Today's votes by the Advisory Committee bring our Company one step closer to adding an important vaccine to our portfolio."

To date, the company has submitted regulatory applications for Prevenar 13* (Pneumococcal Polysaccharide Conjugate Vaccine [13-valent, Adsorbed]), as it is known outside the U.S., in 60 countries spanning six continents. The vaccine has been approved in three countries for use in infants and young children. In late September, the European Medicines Agency’s (EMEA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion for Prevenar 13. A final decision is expected by European regulatory authorities in December. Additionally, the vaccine is being studied in global Phase III clinical trials for the prevention of pneumococcal disease 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 S. 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.

Indication for Prevnar®

Prevnar is indicated for active immunization of infants and toddlers against invasive disease caused by S. pneumoniae due to capsular serotypes included in the vaccine (4, 6B, 9V, 14, 18C, 19F, and 23F). The routine schedule is 2, 4, 6, and 12 to 15 months of age.

The decision to administer Prevnar should be based primarily on its efficacy in preventing invasive pneumococcal disease. As with any vaccine, Prevnar may not protect all individuals receiving the vaccine from invasive pneumococcal disease.

Prevnar is also indicated for active immunization of infants and toddlers against otitis media caused by serotypes included in the vaccine. However, for vaccine serotypes, protection against otitis media is expected to be substantially lower than protection against invasive disease. Additionally, because otitis media is caused by many organisms other than serotypes of S. pneumoniae represented in the vaccine, protection against all causes of otitis media is expected to be low.

This vaccine is not intended to be used for treatment of active infection.

Important Safety Information for Prevnar®

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 Prevnar. Hypersensitivity to any vaccine component, including diphtheria toxoid, is a contraindication to its use. Prevnar does not provide 100% protection against vaccine serotypes or protect against nonvaccine serotypes. The decision to administer Prevnar 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 November 18, 2009. Pfizer assumes no obligation to update any 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 more than 60 countries in which the company has submitted regulatory applications, including the U.S.; 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 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.

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