Study Shows Prevenar 13* Is Immunogenic In Young Children Previously Vaccinated With Prevenar*

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Other Data Support the Inclusion of Pneumococcal Serotypes 6A and 19A in Prevenar 13

NEW YORK--(BUSINESS WIRE)--According to results from a Phase III safety and immunogenicity study presented today, Prevenar 13* (Pneumococcal polysaccharide conjugate vaccine, [13-valent, adsorbed]) was shown to be immunogenic and generally well tolerated in healthy young children who had received at least three prior doses of Prevenar* (Pneumococcal Saccharide Conjugated Vaccine, Adsorbed). These data were presented today at the 7th International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) in Tel Aviv, Israel.

Prevenar 13 includes the seven serotypes (4, 6B, 9V, 14, 18C, 19F, and 23F) in Prevenar plus six additional serotypes (1, 3, 5, 6A, 7F, and 19A). Together, these 13 serotypes represent the most prevalent invasive disease-causing strains in young children worldwide.

“Prevenar has significantly reduced the incidence of invasive pneumococcal disease in young children in areas where it is routinely used. The data from this Phase III study showed that children up to 5 years of age previously vaccinated with Prevenar had an increased immune response against all 13 serotypes included in Prevenar 13,” says Robert W. Frenck, Jr., M.D., the study’s coordinating investigator and professor of pediatrics, Cincinnati Children's Hospital Medical Center.

Also presented at this meeting were data comparing immunogenicity and functional antibody responses in young children who were administered Prevenar and Prevenar 13. It has been suggested that pneumococcal conjugate vaccines that include serotypes 6B and 19F may provide some cross protection against invasive disease caused by 6A and 19A. The data presented suggest that the immunogenicity and functional antibody responses induced by Prevenar 13 for serotypes 6A and 19A were greater than the responses elicited by Prevenar. These results are believed to be attributable to the inclusion of these two serotypes in Prevenar 13.

“These data further suggest the importance of providing direct coverage against the 13 most common pneumococcal disease-causing serotypes worldwide,” says Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer Inc. “Notably, serotypes 6A and 19A, which are included in Prevenar 13, are prevalent in many regions of the world.”

About the Studies

Abstract #153: Immunogenicity and Safety of 13-valent Pneumococcal Conjugate Vaccine in Children Previously Immunized with 7-valent Pneumococcal Conjugate Vaccine

This abstract pertained to an open-label Phase III study that was conducted to evaluate the immune response of 307 children between the ages of 15 months and 5 years who received at least three prior doses of Prevenar (the evaluable immunogenicity population). The study measured immunoglobulin G (IgG) and response was assessed as greater than or equal to 0.35 mcg/mL for each of the Prevenar 13 serotypes measured one month after the last scheduled vaccination (the study’s primary endpoint).

The study showed that children aged >15 months to <2 years who received two doses of Prevenar 13 responded to vaccination with Prevenar 13 with a high proportion of responders to the six additional serotypes included in the vaccine, ranging from 94.5 percent (serotype 3) to 100 percent (serotypes 1, 7F and 19A, n=126). In children ≥2 to ≤5 years old who received one dose of Prevenar 13, response to vaccination was also high for the six additional vaccine serotypes with proportion of responders ranging from 92 percent (serotype 3) to 100 percent (serotype 19A, n=181). Children in both age groups also experienced a booster effect of increased immunity against the seven common serotypes in both vaccines.

In addition, data from the study showed that Prevenar 13 was generally well tolerated. The most commonly reported adverse reactions were injection-site reactions, fever, irritability, decreased appetite, and increased and/or decreased sleep. Most local reactions were mild and lasted approximately two days.

Abstract #572: Immunity to Serogroups 6 and 19 by CRM197-based PCV7 and PCV13: The Relative Importance of Direct and Cross Protection

This abstract described data from five Phase III pediatric clinical studies conducted in the United States and Europe that assessed and compared the immune responses to serotypes 6A and 19A for infants and toddlers vaccinated with Prevenar and Prevenar 13. Children in the studies received immunizations of either three infant doses followed by a toddler dose or two infant doses followed by a toddler dose, according to the National Vaccine Program in each country. Immune responses to serotypes 6A and 19A were analyzed by testing blood samples using ELISA anticapsular IgG (GMCs and percent responders achieving the World Health Organization-established threshold of greater than or equal to 0.35 mcg/mL) and functional opsonophagocytic assay (OPA) after vaccination with Prevenar or Prevenar 13.

The data showed concordance between IgG and OPA activity to serotype 6A with both Prevenar and Prevenar 13, but the functional antibody response induced by Prevenar 13 was four to 25 times greater than that for Prevenar.

Moreover, although Prevenar elicited IgG antibody responses to serotype 19A, it elicited only a negligible functional response. Prevenar 13 IgG responses were 1.3 to 2.5 times greater than Prevenar and Prevenar 13 showed a marked anti-type 19A functional OPA activity.

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 infants and young children and includes invasive infections such as bacteremia/ sepsis and meningitis, as well as pneumonia and acute otitis media.

Indication for Prevenar 13

Prevenar 13 is indicated for the prevention of invasive disease, pneumonia, and otitis media caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F in infants and children from 6 weeks to 5 years of age.

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 nonvaccine 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.

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