Pfizer’s Prevnar 13® Meets All Study Endpoints In Two Pivotal Phase 3 Trials In Adults Aged 50 And Older Presented Today

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(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) today announced that the data from its two pivotal Phase 3 immunogenicity and safety trials of Prevnar 13®* (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) in adults aged 50 years and older met all study endpoints. These studies provide the clinical foundation for the regulatory filings that have been submitted in the United States, the European Union and more than a dozen other countries. The results are being presented today at the 21st European Congress of Clinical Microbiology and Infectious Diseases and the 27th International Congress of Chemotherapy (ECCMID/ICC) in Milan, Italy.

Highlighting the results, the data from both studies showed that Prevnar 13 was at least as immunogenic as the currently licensed nonconjugated pneumococcal polysaccharide vaccine (PPSV) for the 12 serotypes common to both vaccines in the age groups studied who were either pneumococcal vaccine-naïve or previously immunized with PPSV. Furthermore, the secondary endpoint data from both studies showed that Prevnar 13 elicited a statistically significantly higher functional antibody response than PPSV against a majority of serotypes common to both vaccines and serotype 6A, a serotype not contained in PPSV.

“Both pivotal studies met their primary objectives and demonstrated that Prevnar 13 was at least as immunogenic to PPSV for the 12 disease-causing serotypes common to both

vaccines,” says Lisa A. Jackson, MD, MPH, principal investigator, Group Health Research Institute, Seattle, Washington. “The data also showed that Prevnar 13 induced significantly higher levels of functional antibodies than PPSV in the adults studied for the majority of the common serotypes.”

Prevnar 13, which is based on the scientific foundation of Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), was first introduced in December 2009 in Europe and is now approved for use in infants and young children in more than 90 countries worldwide. Prevnar 13, like Prevnar, uses company-pioneered conjugation technology that has been shown to confer a high antibody response in infants and toddlers.

“Prevnar 13 represents an important scientific achievement and we are excited about the potential to further define its clinical utility with the aim of broadening pneumococcal disease prevention efforts,” says Emilio Emini, PhD, chief scientific officer, Vaccine Research, Pfizer Inc. “Adults 50 years and older are a population at heightened risk for pneumococcal disease, which imposes a significant public health and economic burden worldwide.”

Pivotal Data:

The data being presented at ECCMID/ICC are from two pivotal studies in the Prevnar 13 adult Phase 3 clinical trial program, which is comprised of a total of six studies involving approximately 6,000 adults aged 50 years and older.

Study 004 (Abstract #426) is a randomized, double-blind, Phase 3 trial comparing the immunogenicity of a single dose of Prevnar 13 to that of a single dose of PPSV in 835 pneumococcal vaccine-naïve adults aged 60 to 64 years. The study also included an additional group of 404 adults aged 50 to 59 years who received open-label Prevnar 13. For all subjects, serotype specific anti-pneumococcal opsonophagocytic antibody (OPA) titers, also called functional antibodies, were measured prior to vaccination, as well as at one month following vaccination. The results showed that:

Prevnar 13 was at least as immunogenic as PPSV for all serotypes common to both vaccines in the 60 to 64 year age group. In addition, one dose of Prevnar 13 in this age group induced a functional antibody response that was statistically significantly higher than that elicited by PPSV for the majority (8 of 12) of serotypes common to both vaccines, as well as for serotype 6A, a serotype included only in Prevnar 13. In the open-label phase of the study comparing the functional antibody response following administration of Prevnar 13 in adults aged 50 to 59 years to adults aged 60 to 64 years,

Prevnar 13 in the younger age group was as immunogenic as Prevnar 13 in the older age group for all vaccine serotypes contained in the vaccine. In addition, the antibody response was statistically significantly higher for 9 of the 13 serotypes in adults aged 50 to 59 years compared to those aged 60 to 64 years. The tolerability and safety profile of Prevnar 13 was comparable to PPSV for all age groups studied. Among subjects 60 to 64 years of age, local reactions (e.g., swelling, redness, etc.) were reported by 82 percent of subjects in the Prevnar 13 group and by 76 percent of subjects in the PPSV group (P=0.05).

Study 3005 (Abstract #425) is a randomized, double-blind, Phase 3 trial comparing the immunogenicity of Prevnar 13 to that of PPSV in 938 adults 70 years of age and older who had previously been vaccinated with PPSV at least five years earlier. At enrollment, subjects were vaccinated with either Prevnar 13 or PPSV. One year later, all subjects received a follow-on administration of Prevnar 13. For all subjects, serotype specific anti-pneumococcal OPA titers were measured prior to vaccination, as well as one month following each vaccination. The results showed that:

The initial administration of Prevnar 13 was at least as immunogenic as PPSV for all serotypes common to both vaccines. The functional antibody response elicited by Prevnar 13 was statistically significantly higher than that elicited by PPSV for the majority (10 of 12) of serotypes common to both vaccines, as well as for serotype 6A, a serotype included only in Prevnar 13. A follow-on dose of Prevnar 13 administered one year later to subjects who had received a first dose of Prevnar 13 was at least as immunogenic as the initial dose of Prevnar 13 for all 13 serotypes; however, when Prevnar 13 was administered one year after the study dose of PPSV, the functional antibody response for the majority of serotypes was less robust compared to a single dose of Prevnar 13. The functional antibody response after the follow-on administration of Prevnar 13 in subjects who received an initial dose of Prevnar 13 compared with the Prevnar 13 response in subjects who had received an initial study dose of PPSV was statistically significantly higher for the majority (12 of 13) of serotypes. The tolerability and safety profiles of the two vaccine groups were comparable. After the enrollment vaccination, local reactions were reported by 57 percent of subjects in the Prevnar 13 group and by 64 percent of subjects in the PPSV group (P=0.03). After the Prevnar 13 dose given at one year, the frequency and severity of local reactions were similar between the Prevnar 13/Prevnar 13 and the PPSV/Prevnar 13 sequence groups.
Pfizer has submitted supplemental applications seeking regulatory approval to expand the use of Prevnar 13 to adults aged 50 years and older in more than 40 countries around the world with additional submissions planned.

Pneumococcal Disease

Pneumococcal disease is a group of illnesses caused by the bacterium Streptococcus pneumoniae (S. pneumoniae), also known as pneumococcus.1 It includes invasive infections such as bacteremia, sepsis, and meningitis, as well as non-invasive infections, such as pneumonia and otitis media. Pneumococcal disease is a major cause of illness and death in adults worldwide.

Indication for Prevnar 13 for Pediatric Use in the United States

In the United States, 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 for Pediatric Use in the United States

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 commonly reported serious adverse events include bronchiolitis (an infection of the lungs) (0.9%, 1.1%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%, 0.9%), and pneumonia (0.9%, 0.5%) for Prevnar 13 and Prevnar, respectively. 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. Ask your child's health care provider about the risks and benefits of Prevnar 13. Only a health care provider can decide if Prevnar 13 is right for your child.

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 May 9, 2011. 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 adults in the various countries in which the Company's regulatory applications are pending, including the U.S. and European Union; 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 other countries for a potential indication for Prevnar 13 for use in adults; whether and when the FDA, the European Medicines Agency and regulatory authorities in other jurisdictions will approve applications that have been or may be submitted for this potential indication and their decisions regarding labelling and other matters that could affect its availability or commercial potential; 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, 2010 and in its reports on Form 10-Q and Form 8-K.

*Prevnar 13 is referred to as Prevenar 13 in most countries outside the United States.

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