Pfizer Announces Top-Line Results Of Prevenar 13® Phase 3 Trial In Adults 18 To 49 Years Of Age

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Data Support EU Regulatory Filing and Planned Worldwide Regulatory Filings For This Age Group

"The clinical program for Prevenar 13 demonstrates our commitment to developing vaccines that can prevent serious disease through every stage of life,"

(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) today announced top-line data assessing immunogenicity, tolerability and safety of Prevenar 13®* (Pneumococcal polysaccharide conjugate vaccine [13-valent, absorbed]) in adults 18 to 49 years of age. These data support a recent regulatory submission to expand the indication of Prevenar 13 in the European Union to include adults between 18 and 49 years old, and will be used to support similar planned submissions in other countries around the world in the future.

The primary objective of this study was to demonstrate that the immune response to Prevenar 13 in the 18 to 49 year old age group is noninferior to the immune response to Prevenar 13 in the 60 to 64 year old age group as measured by serotype specific opsonophagocytic assay (OPA) titers one month after vaccination. The primary objective was met for all 13 serotypes in Prevenar 13.

“The clinical program for Prevenar 13 demonstrates our commitment to developing vaccines that can prevent serious disease through every stage of life,” said William Gruber, M.D., senior vice president, Vaccine Clinical Research and Development, Pfizer Inc. “Prevenar 13 is the first and only pneumococcal conjugate vaccine for adults, and we continue to study the vaccine in new populations with the aim of broadening its

availability.”

Pneumococcal disease is associated with significant mortality and morbidity for individuals of all ages. Prevenar 13 provides the broadest coverage of any pneumococcal conjugate vaccine and has proven effectiveness against invasive pneumococcal disease in children less than 2 years of age when used as part of a routine pediatric immunization program.

Prevenar 13 is currently approved in more than 110 countries worldwide for use in infants and young children and in more than 70 countries for use in adults 50 years of age and older. Prevenar 13 also is available through the World Health Organization (WHO) pre-qualification program for active immunization of infants and young children, as well as adults 50 years and older.

About the Study

Study 6115A1-004 is a pivotal, Phase 3, multi-center trial designed to compare the immunogenicity, tolerability and safety of Prevenar 13 and the currently licensed nonconjugated pneumococcal polysaccharide vaccine (PPSV) in 740 adults 60 to 64 years of age who were naïve to PPSV, using a randomized, modified double-blind design. The study also assessed immunogenicity, tolerability and safety of Prevenar 13 administered open-label to 370 adults 50 to 59 years of age and compared to adults 60 to 64 years of age. Additionally, 900 healthy adults 18 to 49 years of age (patients with stable chronic risk conditions were eligible for inclusion) were assessed. These participants received open-label Prevenar 13 to assess the immune response to Prevenar 13 in that younger age group and to compare immune responses with participants 60 to 64 years of age. Serotype specific anti-pneumococcal functional antibodies were measured for all 18 to 49 year old participants prior to vaccination, at one month following vaccination and again at one year following vaccination with Prevenar 13.

A detailed analysis of this immunogenicity and safety study data will be submitted for future publication. Data concerning the 50 years of age and older cohorts were previously presented at the 21st European Congress of Clinical Microbiology and Infectious Diseases in 2011.

About Prevenar 13 and Conjugate Technology

Prevenar 13 uses Company-pioneered conjugate technology that links pneumococcal polysaccharide sugar chains found on the surface of each bacterial serotype with a carrier protein. Prevenar 13 uses the carrier protein CRM197, which has more than 20

years of clinical and commercial use in vaccines.

Pneumococcal Disease

Pneumococcal disease (PD) is a group of illnesses caused by the bacterium Streptococcus pneumoniae (S. pneumoniae), also known as pneumococcus. It can affect people of all ages, although older adults, young children and individuals with certain chronic medical conditions are at heightened risk. PD is associated with significant morbidity and mortality. Non-invasive PD includes non-bacteremic pneumococcal pneumonia (acute lower respiratory infection that affects the lungs), which is the most common form of PD in adults, as well as sinusitis (upper respiratory tract infection) and acute otitis media (middle ear infection, most often found in children). Invasive manifestations of the disease include bacteremic pneumonia (lung infection with bacteria in the blood), bacteremia (bacteria in the blood) and meningitis (infection of the tissues surrounding the brain and spinal cord).

EU Indications for Prevenar 13

In the European Union, Prevenar 13 is indicated for active immunization for the prevention of invasive pneumococcal disease caused by Streptococcus pneumoniae in adults aged 50 years and older caused by 13 Streptococcus pneumoniae serotypes. The vaccine is also indicated for active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants and children from 6 weeks to 5 years of age.

For a global summary of Prevenar 13 characteristics (SmPC), please click here http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001104/WC500057247.pdf

U.S. Indications for Prevnar 13

Prevnar 13 is a vaccine indicated for adults 50 years of age and older for the prevention of pneumococcal pneumonia and invasive disease caused by 13 Streptococcus pneumoniae strains (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). This indication is based upon immune responses to the vaccine In children 6 weeks through 5 years of age, Prevnar 13 is indicated for the prevention of invasive disease caused by these same strains, and for the prevention of ear infection caused by 7 of the 13 strains Prevnar 13 is not 100% effective and will only help protect against the 13 strains included in the vaccine Effectiveness when given less than 5 years after a pneumococcal polysaccharide vaccine is not known

Important Safety Information

Prevnar 13 should not be given to anyone with a history of severe allergic reaction to any component of Prevnar 13 or any diphtheria toxoid–containing vaccine Children and adults with weakened immune systems (e.g., HIV infection, leukemia) may have a reduced immune response In adults, the common side effects were pain, redness, or swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, chills, or rash In adults, immune responses to Prevnar 13 were reduced when given with injected seasonal flu vaccine A temporary pause of breathing following vaccination has been observed in some infants born prematurely The most commonly reported serious adverse events in children were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%) In infants and toddlers, the most common side effects were tenderness, redness or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever Ask your health care provider about the risks and benefits of Prevnar 13. Only a health care provider can decide if Prevnar 13 is right for you
For the full prescribing information for Prevnar 13, please click here http://www.pfizer.com/products/#prevnar13

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DISCLOSURE NOTICE: The information contained in this release is as of October 4, 2012. 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 adults 18 to 49 years of age, including its potential benefits. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by the European Commission and by regulatory authorities in other jurisdictions in which applications may be filed regarding whether and when to approve this potential indication as well as their decisions regarding labeling and other matters that could its affect the availability and 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, 2011 and in its reports on Form 10-Q and Form 8-K.

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

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